

EPA Registration No. 90332-2



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL
SAFETY AND POLLUTION
PREVENTION

January 30, 2015


I, Hope Johnson, Fungicide Branch, Registration Division, Office of Pesticide Programs, Office of Chemical Safety and Pollution Prevention, United States Environmental Protection Agency ("EPA"), certify that the pesticide product(s) listed below is, as of the date of this letter, a registered product under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, and that as such, the product(s) may be sold and marketed in the United States of America as authorized and limited by FIFRA. A true and correct copy of the product label approved by EPA is attached to accompany this letter.

Registration of this product(s) with EPA also denotes that the registrant listed below is responsible for ensuring full compliance with all the laws of the United States of America, or governing jurisdiction, regarding the sale, storage and/or disposal of the product(s). Further, the recipient of this letter is on notice that the referenced registration and/or the accompanying label may change subsequent to the date of this letter. EPA assumes no responsibility to notify the recipient(s) (i.e., Lebanon) of this letter of any change in the status of the registration(s) and/or the product label for the product(s) listed below.

EPA has issued registration numbers for the product(s) listed below to:

Zenith Crop Sciences, S.A.
Aubundt 36
FL 9490 Vaduz, Liechtenstein

EPA Registration Number: 90332-2
Name of Product: cY MANCO 4-40 WDG FUNGICIDE


Hope Johnson
Risk Manager 21
Fungicide Branch
Registration Division ()





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EPA Registration Number: 90332-2
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Hope Johnson
Risk Manager 21
Fungicide Branch
Registration Division ()





United States
Environmental Protection Agency
Washington, DC 20460

Registration
Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number Zenith Crop Sciences / 90332-2	2. EPA Product Manager Hope Johnson	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Zenith Crop Sciences / CY-MANCO 4-40 WDG	PM# 21	
5. Name and Address of Applicant (Include ZIP Code) Zenith Crop Sciences S.A. Aubündt 36, FL 9490 Vaduz, Liechtenstein <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Request 3 copies Gold Seal certificate for 90332-2, 1 for use in Morocco, 1 for Tunisia, 1 for Lebanon

Please send letters to D. O'Shaughnessy Consulting, 427 Hide Away Circle, Cub Run, KY 42729

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	
* Certification must be submitted				<input type="checkbox"/> Plastic	
If "Yes" Unit Packaging wgt. No. per container		If "Yes" Package wgt. No. per container		<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input checked="" type="checkbox"/> Other (Specify)	Foil-lined paper bag
3. Location of Net Contents Information <input type="checkbox"/> Label <input checked="" type="checkbox"/> Container		4. Size(s) Retail Container 2 Kg, 15 Kg, 25 Kg.		5. Location of Label Directions <input type="checkbox"/> On Label <input checked="" type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product		<input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)				
Name Don O'Shaughnessy		Title Agent		
		Telephone No. (Include Area Code) (270) 524-5633		
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Applicant Received (Stamped)	
2. Signature 		3. Title Agent		
4. Typed Name Don O'Shaughnessy		5. Date 01/22/2014		

Receipt for Section 3

S: 963437

Milestone Email:

Regulatory Type: Product Registration - Section 3

Resubmission: ☐ Yes ☒ No

Application Type: Amendment

Fee For Service: ☒ Yes ☐ No

Company: 90332 ZENITH CROP SCIENCES, S.A.

Billable: ☒ Yes ☐ No

Risk Manager: Registration Division, Risk Management Team 21

Product #: 90332-2

Product Name: cY MANCO 4-40 WDG FUNGICIDE

Override#:

Me Too Section3:

Me Too Product Name:

Application Date: 22-Jan-2015

OPP Rec'd Date: 28-Jan-2015

Front End Date: 28-Jan-2015

Risk Manager Send Date: 28-Jan-2015

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

Gold Seal Certificate for Morocco, Tunisia and Lebanon.

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:

New Ingredient Request Date:

New Ingredient Received Date:

View/Edit

Print Letter

Enter More Information

Tracking

Receipt Content	Des
Other	Gold Seal



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

January 28, 2015

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OPP Decision Number: D-499436
EPA File Symbol or Registration Number: 90332-2
Product Name: cY MANCO 4-40 WDG FUNGICIDE
EPA Receipt Date: 28-Jan-2015
EPA Company Number: 90332
Company Name: ZENITH CROP SCIENCES, S.A.

DON O'SHAUGHNESSY, PH.D
D. O'SHAUGHNESSY CONSULTING, INC
ZENITH CROP SCIENCES, S.A.
427 HIDE AWAY CIRCLE
CUB RUN, KY 42729-

SUBJECT: Receipt of Request for Gold Seal Certification Letter(s)

Dear Registrant:

The Office of Pesticide Programs has received your request for Gold Seal Certification letter(s) that is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The action has been identified as action code M006:

UP TO 5 GOLD SEAL CERTIFICATION LETTERS PER REGISTRATION

No additional payment is due at this time. If you have any questions, please contact Betty Williams at (703) 308-0132.

Sincerely,

Front End Processing Staff
Information Technology & Resources Management Division

Commercial/financial information may be entitled to confidential treatment

D. O'SHAUGHNESSY CONSULTING, INC.

427 HIDE AWAY CIRCLE
CUB RUN, KY 42729-8692
(270) 524-5633

2758

73-36-839

DATE

1/26/2015

PAY
TO THE
ORDER OF

US-EPA

\$ 526.00

FIVE-HUNDRED-TWENTY-SIX-AND

XX
100

DOLLARS

Security Features
Printed on Back

usbank.

All of us serving you

FOR GOLD SEAL CERTS (2@ 163)

[Signature]

002758

PROCESSING REQUEST

Reg # 90332-2

Decision #

Description: New Product Registration

Material Available Electronically (see PPLS):

☒ Electronic Label/Letter Dated 12/17/2014

☐ Other:

Material Sent (see jacket):

☐ Stamped Label/Letter Dated

☐ Notification Dated

☐ New CSF(s) Dated

☐ Other:

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Tamue L. Gibson, M.S.

Division: Registration

Phone: 30509096

Date:



U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs
Registration Division (7505P)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

EPA Reg. Number:

90332-2

Date of Issuance:

12/17/2014

NOTICE OF PESTICIDE:

☒ Registration
☐ Reregistration
(under FIFRA, as amended)

Term of Issuance:

Conditional

Name of Pesticide Product:

CY-MANCO 4-40 WDG
Fungicide

Name and Address of Registrant (include ZIP Code):

Zenith Crop Sciences, S.A.
Aubunt 36, PO Box 880
FL 9490 Vaduz, Liechtenstein

Mailed To:

Dr. Don O'Shaughnessy
D. O'Shaughnessy Consulting, Inc.
427 Hide Away Circle
Cub Run, KY 42729

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A). You must comply with the following conditions:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official:

Hope A. Johnson, Product Manager 21
Fungicide Branch, Registration Division (7505P)

Date:

12/17/2014

2. You are required to comply with the data requirements described in the DCI identified below:

a. Cymoxanil GDCI-129106-1202.

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI listed above, you may contact the Chemical Review Manager in the Pesticide Reevaluation Division: http://www.epa.gov/oppsrrd1/contacts_prd.htm

3. Make the following label changes before you release the product for shipment:

- Revise the EPA Registration Number to read, "EPA Reg. No. 90332-2."
- Add appropriate Net Contents information to the label

4. Submit one copy of the final printed label for the record before you release the product for shipment.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. Please also note that the record for this product currently contains the following CSFs:

- Basic CSF dated 7/28/2014
- Alternate CSF #1 dated 7/28/2014
- Alternate CSF #2 dated 7/28/2014
- Alternate CSF #3 dated 7/28/2014
- Alternate CSF #4 dated 7/28/2014
- Alternate CSF #5 dated 7/28/2014
- Alternate CSF #6 dated 7/28/2014
- Alternate CSF #7 dated 7/28/2014

Page 3 of 3
EPA Reg. No. 90332-2
Decision No. 486410

If you have any questions, please contact Tamue L. Gibson at (703) 305-9096 or gibson.tamue@epa.gov.

Hope A. Johnson, Product Manager 21
Fungicide Branch
Registration Division (7505P)

Attachments:

- Product Chemistry Review of New End Use Product, dated September 22, 2014, D422647
- Product Chemistry Review of New End Use Product, dated July 24, 2014, D418416
- Acute Toxicity Data Evaluation Record (DER) for CY-Manco 4-40 WDG Fungicide dated July 1, 2014, DP Barcode D418416

CY-MANCO 4 - 40 WDG FUNGICIDE

ACTIVE INGREDIENT:

Mancozeb (a coordination product of zinc ion and manganese ethylenebisdithiocarbamate)	40.0 %
manganese++	8.0%
zinc	1.0%
ethylenebisdithiocarbamate ion	31.0%
Cymoxanil	4.0 %
OTHER INGREDIENTS	56 %
TOTAL:	100.0 %

ACCEPTED

12/17/2014

Under the Federal Insecticide, Fungicide
and Rodenticide Act as amended, for the
pesticide registered under
EPA Reg. No. 90332-2

KEEP OUT OF REACH OF CHILDREN

CAUTION

FIRST AID
IF ON SKIN <ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.• Call a poison control center or doctor for treatment advice.
IF SWALLOWED: <ul style="list-style-type: none">• Call poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to by the poison control center or doctor.• Do not give anything to an unconscious person.
IF IN EYES: <ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15 to 20 minutes.• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a poison control center or doctor for treatment advice.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. FOR CHEMICAL EMERGENCY: Spill, leak, fire, exposure, or accident call CHEMTREC at 1-800-424-9300.
This product contains mancozeb and ETU, chemicals known to the State of California to cause cancer. ETU is also known to the State of California to cause birth defects or other reproductive harm.

EPA Reg. No. 90332- E

EPA Est. No. 90332-BGR-1

Net Contents _____

Batch No. _____

Manufactured For:
Zenith Crop Sciences, S.A.
Aubundt 36, PO Box 880
FL 9490 Vaduz, Liechtenstein
tel. 00359 888 576 735

Product of Bulgaria

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION

Harmful if absorbed through skin. Harmful if swallowed. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

Personal Protective Equipment (PPE)

Some materials that are chemical-resistant to this product are nitrile rubber, natural rubber, or butyl rubber.

Mixers, loaders, applicators and other handlers must wear:

- long-sleeved shirt
- long pants
- shoes and socks
- chemical-resistant gloves made of any waterproof material.

In addition, for aerial application of CY-MANCO 4-40 FUNGICIDE on lettuce (leaf and head), occupational handlers performing mixing / loading operations must wear a particulate respirator with an N, R, P or HE filter NIOSH approval prefix TC-84A. See engineering controls for additional requirements.

User Safety Requirements

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry. Discard clothing and other absorbed materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them.

Engineering Controls

Enclosed Cockpits: Pilots must use an enclosed cockpit that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d) (4-6)].

Mechanical Flagging Engineering Controls: Human flagging is prohibited. Flagging to support aerial application is limited to use of the Global Positioning System (GPS) or mechanical flaggers.

User Safety Recommendations

Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.
- Remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to aquatic organisms. Drift and runoff from treated areas may be hazardous to aquatic organisms in neighboring areas. Do not apply directly to water, or to areas where surface water is present, or to intertidal areas below the mean high water mark. Do not contaminate water when cleaning equipment or disposing of equipment washwaters or rinsate. For guidance, contact your State Water Board or Regional Office of the Environmental Protection Agency.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your state or tribe, consult the agency responsible for pesticide regulation.

Agricultural Use Requirements

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR Part 170. This standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted-entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI). The REI for each crop is located within the use directions for each crop.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, oil or water, is:

- Coveralls
- Chemical-resistant gloves made of any waterproof material
- Shoes plus socks

PRODUCT INFORMATION

Read all Directions For Use carefully before applying.

Apply as a spray with ground, or air equipment using specified amounts of water to obtain through coverage to plants. Use only commercial or farm plantings. Not for use in residential plantings, or once any commercial crop is turned into U-pick, Pick Your Own or similar operation. For ground application, apply a minimum of 20 gallons of water per acre, increasing the spray volume as the plants mature to ensure through coverage of plant foliage.

For air assisted ground application, apply a minimum of 10 gallons of water per acre.

For aerial application, apply a minimum of 2 gallons of water per acre.

On vegetable and field crops, 2 to 3 gallons of spray per acre are generally optimum; orchards and vineyards can be handled with spray volumes of 5 gallons per acre. Some tall or dense foliage crops requiring greater penetration to the lower leaf surface will require higher spray volumes. Do not apply this product in fewer than 5 gallons spray volume per acre in California.

PRODUCT MIXING INSTRUCTIONS

- 1) Fill the spray tank to 1/4 to 1/3 full of water.
- 2) While agitating, add the specified amounts of CY MANCO 4-40 FUNGICIDE to the spray tank.
- 3) Continue agitating until CY MANCO 4-40 FUNGICIDE is fully dispersed, at least 5 minutes.
- 4) Apply CY MANCO 4-40 FUNGICIDE spray mixture within 12 hours of mixing to avoid product degradation.

SPRAY DRIFT MANAGEMENT

A variety of factors including weather conditions (i.e. wind direction, wind speed, temperature, relative humidity) and method of application (i.e. ground, aerial, airblast, chemigation) can influence pesticide drift. The application must evaluate all factors and make appropriate adjustments when applying this product.

WIND SPEEDS

Do not apply at wind speeds greater than 15 miles per hour (mph).

TEMPERATURE INVERSIONS

If applying at wind speeds less than 3 mph, the applicator must determine if a) conditions of temperature inversion exist, or b) stable atmospheric conditions exist at or below nozzle height. Do not make applications into areas of temperature inversions or stable atmospheric conditions.

OTHER STATE AND LOCAL REQUIREMENTS

Applications must follow all state and local pesticide drift requirements regarding application of mancozeb where states have more stringent regulations, they must be observed.

EQUIPMENT

All aerial and ground application equipment must be properly maintained and calibrated using appropriate carrier or surrogates.

Additional requirements for aerial applicators:

1. The boom length must not exceed 75% of the wing span or 90 % of the rotor blade diameter.
2. Release spray at the lowest height consistent with efficacy and flight safety. Do not release spray at a height greater than 10 feet above the crop canopy unless a greater height is required for aircraft safety.
3. When applications are made with a crosswind, the swath must be displaced down wind. The applicator must compensate for this displacement at the up and downwind edge of the application area by adjusting the path of the aircraft upwind.

Additional requirements for ground boom application:

1. Do not apply with a nozzle height greater than 4 feet above the crop canopy.

Application

Ground

Thorough coverage with foliar sprays generally results in optimum diseases control. To achieve satisfactory coverage use proper spray pressure, volume of spray mixture per acre, nozzles (generally hollow cone), disc (generally D-5 to D-7), nozzle spacing, and tractor speed. Consult spray nozzle and accessory catalogues for specific information on proper equipment calibration.

Hand Sprayers

Thoroughly spray plant foliage until runoff.

Aerial

For aerial application of CY MANCO 4-40 FUNGICIDE to lettuce (head and leaf), occupational handlers performing mixing / loading operations must wear a particulate respirator with an N, R, P or HE filter NIOSH approval prefix TC-84A.

A uniform initial spray deposit over the crop canopy generally results in optimum disease control. Each aircraft should be pre-checked for droplet size, uniformity of spray pattern, swath width, and spray volume. During aerial application, human flaggers are prohibited.

Nozzle selection: Hollow cone brass nozzles with a D-series orifice disc and core (whirlplate) are recommended. Nozzles should point straight down or slightly backward.

Swath width: For most field and vegetable crops, swaths just beyond the wingspan of 36 to 40 feet for light aircraft and up to 45 feet for heavier aircraft are suggested. Optimum swath for helicopters is usually 5 to 10 feet beyond normal boom length.

Altitude: For most crops, position the spray boom 5 to 10 feet above the crop canopy.

Flagging: Mark swaths at the end of the field with permanent flags. Measure swaths accurately with a chain or other device except when rows can be accurately counted.

Crop Restrictions

Cucurbits, lettuce (head and leaf), potatoes, and tomatoes may be re-planted anytime after CY MANCO 4-40 FUNGICIDE applications. All other crops cannot be planted until 30 days after CY MANCO 4-40 FUNGICIDE application.

Foliar Applications

Where EBDC Products Used Allow the Same Maximum Poundage of Active Ingredient Per Acre Per Season: If more than one product containing an EBDC active ingredient (maneb, mancozeb, or metiram) is used on a crop during the same growing season and the EBDC products used allow the same maximum amount in pounds of active ingredient per acre per season, then the total pounds active ingredient of all such EBDC products used must not exceed any one of the

specified individual EBDC product maximum season pounds of active ingredient allowed per acre.

Where EBDC Products Used Allow Different Maximum Poundage of Active Ingredient Per Acre Per Season:

If more than one product containing an EBDC active ingredient is used on a crop during the same growing season and the EBDC products used allow different maximum poundage of active ingredient per acre per season, and the EBDC products used allow different maximum amount in pounds of active ingredient per acre per season, then the total poundage of all such EBDC products used must not exceed the lowest specified individual EBDC product maximum seasonal poundage of active ingredient allowed per acre.

CROP-USE DIRECTIONS AND RATE TABLE

Crop	Diseases	Rate CY MANCO 4-40 Fungicide (lb/ acre/ application)	Specific Use Instructions	Pre- Harvest Interval (PHI)
Cucurbit Vegetables: (not for use on cucurbits in the state of California) Chayote Chinese Waxgourd Citron melon Cucumber Gherkin Gourd, edible Momordica Spp. Muskmelon Pumpkin Squash, Summer squash, Winter Watermelon	Alternaria leaf Anthracnose Cercospora Leaf spot Downy Mildew Gummy stem blight Scab	3 - 4.7	Begin applications when plants are in the two-leaf stage and repeat at 7 to 10 day interval when conditions are favorable for disease development. Consult State Cooperative Extension Specialist prior to use.	3 days

Melons Cantaloupes Casaba Crenshaw Honeydew Watermelon	Alternaria leaf Anthracnose Downy Mildew Gummy stem Blight Microdochium blight			
Restrictions: <ul style="list-style-type: none"> For ground applications, apply a minimum of 20 gallons of spray volume per acre. For aerial application, apply a minimum of 5 gallons per acre. Do not apply more than 8 applications of CY MANCO 4-40 Fungicide per year. Do not apply more than 28 lbs. of product/A per year. Restricted Entry Interval (REI): 12 hours 				
Crop	Diseases	Rate CY MANCO 4-40 Fungicide (lb/acre/app lication)	Specific Use Instructions	Pre- Harvest Interval (PHI)
Grapes (East of the Rocky Mountains only)	Black rot Bunch rot Phomopsis Downy mildew	3.125	Apply at 7-10 day intervals when conditions are favorable for disease development	66 days
Crop	Diseases	Rate CY MANCO 4-40 Fungicide (lb/acre/app lication)	Specific Use Instructions	Pre- Harvest Interval (PHI)
Lettuce (head and leaf)	Downy Mildew (<i>Bremia lactuca</i>)	3 - 4.7	Apply at 7-10 day intervals when conditions are favorable for disease development	3 days for head lettuce 1 day for leaf lettuce 14 days for head or leaf in the State of California
Restrictions: Note: For lettuce, occupational handlers performing mixing/loading operations must wear a particulate respirator with an N, R, P or HE filter NIOSH approval prefix TC-84A. <ul style="list-style-type: none"> In California, do not apply more than 10.6 lb CY MANCO 4-40 Fungicide (6.4 lb mancozeb ai) per acre per crop. In states other than California, do not apply more than 16 lb CY MANCO 4-40 Fungicide (9.6 lb mancozeb ai) per acre per crop. Do not apply more than 2 applications of CY MANCO 4-40 Fungicide per year. Do not apply more than 28 lbs. of product/A per year. Do not apply this product with a U-boom device. Minimum Retreatment Interval: 7 days. Restricted Reentry Interval (REI): 12 hours 				

Crop	Diseases	Rate CY MANCO 4-40 Fungicide (lb/acre/app lication)	Specific Use Instructions	Pre- Harvest Interval (PHI)
Onions (dry bulb) Garlic Shallots	Botrytis leaf blight Downy mildew Neck rot Purple blotch (not in the state of California) Rust	3.125 - 3.9	Apply at a 7 day interval before disease is expected to appear.	3
Restrictions: <ul style="list-style-type: none"> For ground applications, apply a minimum of 20 gallons of spray volume per acre. For aerial application, apply a minimum of 5 gallons per acre. Do not apply more than 9 applications of CY MANCO 4-40 Fungicide per year. Do not apply more than 32.5 lbs. of product/A per year. Do not apply to exposed bulb. Do not allow spray or drift to contact bulbs after lifting from soil. Restricted Entry Interval (REI): 12 hours. 				
Crop	Diseases	Rate CY MANCO 4-40 Fungicide (lb/acre/app lication)	Specific Use Instructions	Pre- Harvest Interval (PHI)
Potato	Late Blight, Early blight, Brown spot	3	Apply at 7-14 day interval beginning at crop height of 4-6 inches. Use the shorter interval if weather conditions favor disease.	14 days
Restrictions: <ul style="list-style-type: none"> Do not apply within 3 days of harvest in Connecticut, Florida, Maine, Massachusetts, New Hampshire, New York, Ohio, Pennsylvania, Vermont, and Wisconsin. Do not apply more than 7 applications of CY MANCO 4-40 Fungicide per year. Do not apply more than 28 lbs. of product/A per year. For ground applications, apply a minimum of 20 gallons of spray volume per acre. For aerial application, apply a minimum of 5 gallons per acre Restricted Entry Interval (REI): 12 hours. 				
Crop	Diseases	Rate CY MANCO 4-40 Fungicide (lb/acre/app lication)	Specific Use Instructions	Pre- Harvest Interval (PHI)
Tomatoes (not for use in the state of California)	Anthracnose Early blight Gray leaf spot Late blight Leaf mold Septoria leaf spot Bacterial speck and spot	1.4 - 1.87 lb/acre west of the Mississippi River 2.8 - 5.4 lb/acre east of the	Apply at 5-7, day intervals, 5 days if disease is present or conditions are favorable for disease development.	3

		Mississippi River		
Restrictions: Do not apply more than 6 applications of CY MANCO 4-40 Fungicide per year. Do not apply more than 21 lbs. of product/A per year Restricted Entry Interval (REI): 12 hours.				

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Store in a cool, dry place and in such a manner as to prevent cross contamination with other pesticides, fertilizers, food or feed. Store in original containers and out of the reach of children, preferably in a locked storage area. Do not store near heat or open flame. Handle an open container in a manner as to prevent spillage.

If the container is leaking or material is spilled, carefully sweep up and wash exposed area with detergent and water. In spill or leak incidents, keep unauthorized people away.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Disposal: Non-refillable container. Do not re-use or re-fill this container. Completely empty bag into application equipment then offer for recycling if available, or dispose of empty bag in a sanitary landfill.

WARRANTY DISCLAIMER

Zenith Crop Sciences, S.A. warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated on the label when used in strict accordance with the directions, subject to the inherent risks set forth below. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, ZENITH CROP SCIENCES, S.A. MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER EXPRESS OR IMPLIED WARRANTY.

INHERENT RISKS OF USE

It is impossible to eliminate all risks associated with use of this product. Unintended consequences may result because of factors such as use of the product contrary to label instructions, which are beyond the control of Zenith Crop Sciences, S.A. or the Seller. Zenith Crop Sciences, S.A. and the Seller shall not be responsible for any risks caused by the incorporation of this product into an end use product by the Buyer or User. Buyer is solely responsible for any risks created by the end use or uses to which Buyer or a User put this product. All of the foregoing risks shall be assumed by Buyer and User, and Buyer and User agree to hold Zenith Crop Sciences, S.A. and Seller harmless for any claims related to such factors.

LIMITATION OF REMEDIES

To the extent consistent with applicable law, the exclusive remedy for losses or damages resulting from this product (including claims based on contract, negligence, strict liability, or other legal theories), shall be limited to one of the following, at Zenith Crop Sciences, S.A. election:

- (1) Refund of purchase price paid by buyer or user for product bought, or
- (2) Replacement of amount of product used.

In no case shall Zenith Crop Sciences, S.A. be liable for consequential, incidental, or special damages or losses.

The terms of the Warranty Disclaimer above and this Limitation of Remedies cannot be varied by any written or verbal statements or agreements. No employee or sales agent of Zenith Crop Sciences, S.A. or the Seller is authorized to vary or exceed the terms of the Warranty Disclaimer or this Limitation of Remedies in any manner.

United States Environmental Protection Agency
Washington, D.C. 20460
REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

OMB Approval 2070-0174

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company Name and Address E. I. DU PONT DE NEMOURS AND COMPANY (S300/419) 1007 MARKET STREET WILMINGTON, DE 198980001		2. Case # and Name N/A - Cymoxanil Chemical # and Name: 129106 Cymoxanil			3. Date and Type of DCI and Number GENERIC ID # GDCI-129106-1202				
4. Guideline Requirement Number	5. Study Title	P R O T O C O L	Progress Reports			6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response
			1	2	3				
	Environmental Fate Data Requirements (Conventional Chemical)								
835.4100	Aerobic soil metabolism	N				A	PAIRA; TGA I	24	
835.4300	Aerobic aquatic metabolism	N				A	PAIRA; TGA I	24	
835.4400	Anaerobic aquatic metabolism	N				A	PAIRA; TGA I	24	
	Nontarget Plant Protection Data Requirements (Conventional Chemical)								
850.4100	Terrestrial Plant Toxicity (Seedling Emergence) (3)	N				A	TEP	12	
850.4150	Terrestrial plant toxicity, Tier 1 (vegetative vigor) (3)	N				A	TEP	12	
	Terrestrial and Aquatic Nontarget Organisms Data Requirements (Conventional Chemical)								
850.1010	Aquatic invertebrate acute toxicity, test, freshwater daphnids (1)	N				A	DEGR	12	
10. Certification: I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law. Signature and Title of Company's Authorized Representative _____							11. Date _____		
12. Name of Company _____							13. Phone Number _____		

United States Environmental Protection Agency
Washington, D.C. 20460
REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

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4. Guideline Requirement Number	5. Study Title	P R O T O C O L	Progress Reports			6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response
			1	2	3				
	Terrestrial and Aquatic Nontarget Organisms Data Requirements (Conventional Chemical)								
850.1075	Fish acute toxicity test, freshwater and marine (2)	N				A	DEGR	12	
850.2100	Avian acute oral toxicity test	N				A	TGAI	12	
850.5400	Algal toxicity, Tiers 1 and II (2, 3, 4)	N				A	DEGR	12	
SS-1163	Honeybee Larval Toxicity	Y				A	PAI; TGAI	12	

United States Environmental Protection Agency
Washington, D.C. 20460

FOOTNOTES AND KEY DEFINITIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: N/A - Cymoxanil

DCI Number: GDCI-129106-1202

Key: Residue of Concern = Residue of Concern; TEP = Typical End Use Product [TEP]; TGA = Technical Grade Active Ingredient [TGA]; TGA/PAIRA = Technical Grade of the Active Ingredient or Pure Active Ingredient, Radio Labelled; TGA, TEP = Technical Grade of the Active Ingredient or Technical End-Use Product; TGA/PAI = Technical Grade Active Ingredient, Pure Active Ingredient

Use Categories Key:

A - Terrestrial food crop

Footnotes: The following footnotes are referenced in column two (5. Study Title) of the Requirements Status and Registrant's Response form. These footnotes apply in addition to any test notes included in 40 CFR Part 158 with respect to the particular data requirement.

- 1 This study should be done on Degradate IN-W3595.
- 2 There are two studies required under this guideline. One study should be conducted on degradate IN-KQ960 and the other study should be conducted on degradate IN-W3595.
- 3 On June 27, 2012, EPA announced certain revisions in harmonized guideline series 850 - Ecological Effects Tests - including renumbering and other designations or changes for some guideline studies. See "Final Test Guidelines; OCSPP 850 Series; Notice of Availability" 77 FR 38282, June 27, 2012. <http://www.regulations.gov#!documentDetail;D=EPA-HQ-OPPT-2009-0154-0028>
- 4 A study carried out with the freshwater diatom, *Navicula pelliculosa*, is preferable since it is the most sensitive species tested with the parent compound.

5.961961

Gibson, Tamue

From: Don O'Shaughnessy <doctox@mac.com>
Sent: Wednesday, December 17, 2014 2:27 PM
To: Gibson, Tamue
Subject: Re: REQUEST FOR REVISED PRODUCT LABELING: Proposed Product: CY-MANCO 4-40 WDG Fungicide
Attachments: certredatacymanco.pdf; ATT00001.htm

Sorry to be slow - I was out of the office this AM



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number (270) 524-5633 Zenith Crop Sciences, c/o D. O'Shaughnessy Consulting, Inc. 427 Hide Away Circle, Cub Run KY 42729	EPA Registration Number/File Symbol 90332- E
Active Ingredient(s) and/or representative test compound(s) cymoxanil, mancozeb	Date 10/05/2013
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) outdoor food	Product Name CY-MANCO 4 - 4.0 WDG Fungicide

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature

Date

10/05/2013

Typed or Printed Name and Title

Don O'Shaughnessy, Agent

SI 961959

Gibson, Tamue

From: Gibson, Tamue
Sent: Wednesday, December 17, 2014 1:50 PM
To: 'Don O'Shaughnessy'
Cc: Johnson, Hope
Subject: REQUEST FOR REVISED PRODUCT LABELING: Proposed Product: CY-MANCO 4-40 WDG Fungicide

Hi Don. Can you please send a revised "Certification with Respect to Citation of Data" form 8570-34. Under the "Active Ingredient(s) and/or representative test compound(s) section, please include cymoxanil and mancozeb. Please delete the reference to "copper hydroxide".

From: Gibson, Tamue
Sent: Wednesday, November 05, 2014 6:43 PM
To: 'tamuegibson@verizon.net'
Subject: FW: REQUEST FOR REVISED PRODUCT LABELING: Proposed Product: CY-MANCO 4-40 WDG Fungicide

From: Don O'Shaughnessy [<mailto:doctox@mac.com>]
Sent: Thursday, October 23, 2014 3:30 PM
To: Gibson, Tamue
Subject: Re: REQUEST FOR REVISED PRODUCT LABELING: Proposed Product: CY-MANCO 4-40 WDG Fungicide

This should do it ... let me know if not.

On the point of the sub-composition of the mancozeb, the mancozeb-only labels were required to have them inset so as not to be confused as being part of the 100%. I attach a copy of the stamped mancozeb 75 as comparison. I think they should all be consistent, n'est-ce pas?

Also, no reason Ms. Roe should get all the good photos ... How are the fall colors in your neighborhood?

S: 961960

Gibson, Tamue

From: Don O'Shaughnessy <doctox@mac.com>
Sent: Tuesday, December 16, 2014 5:06 PM
To: Gibson, Tamue
Subject: Re: Please REVISE YOUR PRODUCT LABEL (12/16/14): Proposed Product: CY MANCO
4-40 WDG Fungicide
Attachments: CYMANCOLabeldec16-14.pdf; ATT00001.htm
Importance: High

OK, here you go.
And my name is just Don. Or sometimes "you crotchety old fart".

From: Gibson, Tamue
Sent: Tuesday, December 16, 2014 3:28 PM
To: 'Don O'Shaughnessy'
Subject: Please REVISE YOUR PRODUCT LABEL (12/16/14): Proposed Product: CY MANCO 4-40 WDG Fungicide

Importance: High

Hello Dr. O'shaughnessy. Per Hope's conference call today. Please revise your labeling to the following:

1. Revise the entire product labeling to the "Portrait" (vertical) orientation and not "Landscape" (horizontal) orientation.
2. On page 1, revise the 3rd bullet within the "First Aid" statement for "If Swallowed" to read "Do not induce vomiting unless told to by a poison control center or doctor."
3. On page 2, remove the colon after the word "Caution" within the heading for the "Precautionary Statements" HAZARDS TO HUMANS AND DOMESTIC ANIMALS CAUTION"
4. On page 2, delete the 2nd sentence under the "Precautionary Statements" section "Wear long sleeved shirt and long pants, socks, shoes, chemical resistant gloves (such as Natural Rubber, Selection Category A) and protective eyewear (if appropriate). Remove and wash contaminated clothing before reuse."
5. Per the RED document, please underline the following text within your label page 6.

Foliar Applications

Where EBDC Products Used Allow the Same Maximum Poundage of Active Ingredient Per Acre Per Season: If more than one product containing an EBDC active ingredient (maneb, mancozeb, or metiram) is used on a crop during the same growing season and the EBDC products used allow the same maximum amount in pounds of active ingredient per acre per season, then the total pounds active ingredient of all such EDBC products used must not exceed any one of the specified individual EDBC product maximum season pounds of active ingredient allowed per acre.

Where EBDC Products Used Allow Different Maximum Poundage of Active

Ingredient Per Acre Per Season: If more than one product containing an EBDC active ingredient is used on a crop during the same growing season and the EBDC products used allow different maximum poundage of active ingredient per acre per season, then the total poundage of all such EBDC products used must not exceed the lowest specified individual EBDC product maximum seasonal poundage of active ingredient allowed per acre.

6. Within the "Crop Use Directions and Rate Table" for "Lettuce (head and leaf), under "Pre-Harvest Interval (PHI)" add the phrase "for head and leaf" to the following sentence "14 days in the State of California for head and leaf".
7. Within the "Crop Use Directions and Rate Table" for "Tomatoes" under the heading "Rate CY MANCO 4-40 Fungicide" write out the term "acre" for the abbreviated term "ac" so that the value reads "1.4-1.87 lb/acre west of the Mississippi River" and "2.8 – 5.4 lb/acre east of the Mississippi River".
8. On page 6, please remove "lbs." from the value "3 lbs.-4.7 lbs." under the heading "Rate CY MANCO 4-40 Fungicide" for the crop use "Cucurbit Vegetables"

****The END****

From: Don O'Shaughnessy [mailto:doctox@mac.com]

Sent: Sunday, December 14, 2014 4:07 PM

To: Gibson, Tamue

Subject: Re: Please REVISE YOUR PRODUCT LABEL (12/12/14): Proposed Product: CY MANCO 4-40 WDG Fungicide

Importance: High

Luxury? Ouch, that stung. I have precious little of that in my life as an old cripple with one leg.

In any event, once again thank you for your hard work. I attach a new version, formatted just as you prefer. With regard to maximum rates for tomatoes and lettuce, mancozeb is the limiting factor by my calculation, so these have been extrapolated according to the Fortuna 75 WDG label. I went over the previous set of corrections, and found a few places where I had errors or omissions, and I have fixed these. I apologize for missing a few points, which I understand is not ideal for your workload.

But I find that *much* of the content of your email is formatting, rather than substantive. For example, I am not certain that there is *requirement* for alphabetical order of crops rather grouping by crop types, or the orientation onto all vertical columns and no horizontal cells, so long as it is clear to the reader what is required. I formatted that way to save expense - once the label is printed, the printers charge by the page, and placing some lengthy directions horizontally when they would take up a long column and leave vast acres of empty white space in the neighboring columns is highly wasteful of paper and money. In this case, I helped the situation by merely rotating to "landscape" format. Also, repeating the heading row ("Crop...Diseases...Rate.... Specific Use Instructions...PHI") seems highly redundant, and I have never until now seen this required for any other label with a rate table. Of course, that too adds pages and dollars to every label printed.

5:961959

Gibson, Tamue

From: Don O'Shaughnessy <doctox@mac.com>
Sent: Sunday, December 14, 2014 4:07 PM
To: Gibson, Tamue
Subject: Re: Please REVISE YOUR PRODUCT LABEL (12/12/14): Proposed Product: CY MANCO 4-40 WDG Fungicide
Attachments: cymanco440draftDec.14-14.pdf; ATT00001.htm; 2013-14puzzle.jpeg; ATT00002.htm
Importance: High

Luxury? Ouch, that stung. I have precious little of that in my life as an old cripple with one leg.

In any event, once again thank you for your hard work. I attach a new version, formatted just as you prefer. With regard to maximum rates for tomatoes and lettuce, mancozeb is the limiting factor by my calculation, so these have been extrapolated according to the Fortuna 75 WDG label. I went over the previous set of corrections, and found a few places where I had errors or omissions, and I have fixed these. I apologize for missing a few points, which I understand is not ideal for your workload.

But I find that *much* of the content of your email is formatting, rather than substantive. For example, I am not certain that there is *requirement* for alphabetical order of crops rather grouping by crop types, or the orientation onto all vertical columns and no horizontal cells, so long as it is clear to the reader what is required. I formatted that way to save expense - once the label is printed, the printers charge by the page, and placing some lengthy directions horizontally when they would take up a long column and leave vast acres of empty white space in the neighboring columns is highly wasteful of paper and money. In this case, I helped the situation by merely rotating to "landscape" format. Also, repeating the heading row ("Crop...Diseases...Rate.... Specific Use Instructions...PHI") seems highly redundant, and I have never until now seen this required for any other label with a rate table. Of course, that too adds pages and dollars to every label printed.

Anyway, I want this to be done as easily and nicely as possible for both you and me, so I will do just as you wish. Here you go ...

From: Gibson, Tamue
Sent: Friday, December 12, 2014 8:22 PM
To: 'Don O'Shaughnessy'
Subject: Please REVISE YOUR PRODUCT LABEL (12/12/14): Proposed Product: CY MANCO 4-40 WDG Fungicide

Importance: High

Hello Dr. O'Shaughnessy. You still have a lot of work to complete this label for the product to be approved. Please follow each instruction very carefully. Specifically, within the Directions for Use table for each crop you do not have the luxury to change PHI days from the stated number within my email correspondence to you. You also need headings for each crop which include "Crop"; "Diseases" Rate Cy MANCO 4-40 Fungicide (lb/acre/application)" "Pre-Harvest Interval (PHI) Days". Most importantly, the "Specific Use" heading must remain a major heading and must not be placed near the "Restrictions" section.

Please revise your label to the following:

1. On page 1, revise the 3rd bullet within the "First Aid" statement for "If Swallowed" to read "Do not induce vomiting unless told to by a poison control center or doctor."
2. On page 2, remove the colon after the word "caution" within the heading for the "Precautionary Statements" HAZARDS TO HUMANS AND DOMESTIC ANIMALS. The heading must read:

"PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
CAUTION"
3. On page 2, delete the 2nd sentence "If you want more options, follow the instructions for Category A on an EPA chemical resistance category selection chart." Within the "(PPE)" section.
4. Keep the underline text for both paragraphs.

Foliar Applications

Where EBDC Products Used Allow the Same Maximum Poundage of Active Ingredient Per Acre Per Season: If more than one product containing an EBDC active ingredient (maneb, mancozeb, or metiram) is used on a crop during the

same growing season and the EBDC products used allow the same maximum amount in pounds of active ingredient per acre per season, then the total pounds active ingredient of all such EBDC products used must not exceed any one of the specified individual EBDC product maximum season pounds of active ingredient allowed per acre.

Where EBDC Products Used Allow Different Maximum Poundage of Active Ingredient Per Acre Per Season: If more than one product containing an EBDC active ingredient is used on a crop during the same growing season and the EBDC products used allow different maximum poundage of active ingredient per acre per season, then the total poundage of all such EBDC products used must not exceed the lowest specified individual EBDC product maximum seasonal poundage of active ingredient allowed per acre.

5. List each crop in alphabetical order just as I have them listed below with headings.
6. Within the use for "Cucurbit" revise your table to add "Specific Use Instructions as a major heading as well as the other headings for this use.

Crop	Diseases	Rate CY MANCO 4-40 Fungicide (lb/acre/application)	Specific Use Instructions	Pre- Harvest Interval (PHI) Days
Cucurbit Vegetables: (not for use on cucurbits in the state of California) Chayote Chinese Waxgourd Citron melon Cucumber Gherkin Gourd, edible Momordica Spp. Muskmelon	Alternaria leaf Anthracnose Cercospora Leaf spot Downy Mildew Gummy stem Blight scab	3 lbs. – 4.7 lbs.	Begin applications when plants are in the two-leaf stage and repeat at 7 to 10 day interval when conditions are favorable for disease development. Consult State Cooperative Extension	3 days

Pumpkin Squash, Summer squash, Winter Watermelon			Specialist prior to use.	
Melons Cantaloupes Casaba Crenshaw Honeydew Watermelon	Alternaria leaf Anthracnose Downy Mildew Gummy stem Blight Microdochium blight			
Restrictions: <ul style="list-style-type: none"> • For ground applications, apply a minimum of 20 gallons of spray volume per acre. • For aerial application, apply a minimum of 5 gallons per acre. • Do not apply more than 8 applications of CY MANCO 4-40 Fungicide per year. • Do not apply more than 28 lbs. of product/A per year. • Restricted Entry Interval (REI): 12 hours 				

7. Within the use for "Grapes" revise your table to add "Specific Use Instructions as a major heading as well as the other headings for this use:

Crop	Diseases	Rate CY MANCO 4-40 Fungicide (lb/acre/application)	Specific Use Instructions	Pre- Harvest Interval (PHI) Days

Grapes. (East of the Rocky Mountains only)	Black rot Bunch rot Phomopsis Downy mildew	3.125 lbs.	Apply at 7- 10 day intervals when conditions are favorable for disease development	66 days
--	--	------------	--	---------

Restrictions:

- In California, do not apply after bloom.
- East of the Rocky Mountains, do not apply more than 32.8 lbs. of product/A per year.
- For ground applications, apply a minimum of 20 gallons of spray volume per acre.
- For aerial application, apply a minimum of 5 gallons per acre.
- Restricted Entry Interval (REI): 12 hours.

8. Within the use for "Lettuce" revise your table to add "Specific Use Instructions as a major heading as well as the other headings for this use."

9. Within the use for "Lettuce" add the required respirator requirement within the restrictions section.

Note: For lettuce, occupational handlers performing mixing/loading operations must wear a particulate respirator with an N, R, P or HE filter NIOSH approval prefix TC-84A. Within the same crop add the species for Downy Mildew (*Bremia lactuca*)."

10. Within the "Crop Use Directions and Rate Table" for "Lettuce (head and leaf), add the rate restrictions for the state of California and states other than the state of California. Please see an example revised Crop Use Directions and Rate Table for each crop (below).

Crop	Diseases	Rate CY MANCO 4-40 Fungicide (lb/acre/application)	Specific Use Instructions	Pre- Harvest Interval (PHI) Days
Lettuce (head	Downy Mildew	3 lbs. – 4.7 lbs.	Apply at 7- 10 day intervals	3 days for head lettuce

and leaf)	(<i>Bremia lactuca</i>)		when conditions are favorable for disease development	1 day for leaf lettuce 14 days in the state of California
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Restrictions: Note: For lettuce, occupational handlers performing mixing/loading operations must wear a particulate respirator with an N, R, P or HE filter NIOSH approval prefix TC-84A.

- In California, do not apply more than x lb CY MANCO 4-40 Fungicide (x lb ai) per acre per crop.
- In states other than California, do not apply more than x lb CY MANCO 4-40 Fungicide (x lb ai) per acre per crop.
- Do not apply more than 2 applications of CY MANCO 4-40 Fungicide per year.
- Do not apply more than 28 lbs. of product/A per year.
- Do not apply this product with a U-boom device.
- Minimum Retreatment Interval: 7 days.
- Restricted Reentry Interval (REI): 12 hours.

11. Within the use for "Potato" revise your table to add "Specific Use Instructions as a major heading as well as the other headings for this use!

Crop	Diseases	Rate CY MANCO 4-40 Fungicide (lb/acre/application)	Specific Use Instructions	Pre-Harvest Interval (PHI) Days
Potato	Late Blight, Early blight, Brown spot	3 lbs.	Apply at 7-14 day interval beginning at crop height of 4-6 inches. Use the shorter interval if weather conditions	14 days

			favor disease.	
Restrictions: <ul style="list-style-type: none"> Do not apply within 3 days of harvest in Connecticut, Florida, Maine, Massachusetts, New Hampshire, New York, Ohio, Pennsylvania, Vermont, and Wisconsin. Do not apply more than 7 applications of CY MANCO 4-40 Fungicide per year. Do not apply more than 28 lbs. of product/A per year. For ground applications, apply a minimum of 20 gallons of spray volume per acre. For aerial application, apply a minimum of 5 gallons per acre. Restricted Entry Interval (REI): 12 hours. 				

12. Within the use for "Onions (dry bulb) revise your table to add "Specific Use Instructions as a major heading as well as the other headings for this use.

Crop	Diseases	Rate CY MANCO 4-40 Fungicide (lb/acre/application)	Specific Use Instructions	Pre- Harvest Interval (PHI) Days
Onions (dry bulb) Garlic Shallots	Botrytis leaf blight Downy mildew Neck rot Purple blotch (not in the state of California) Rust	3.125 lbs. – 3.9 lbs.	Apply at a 7 day interval before disease is expected to appear.	3 days

Restrictions: <ul style="list-style-type: none"> For ground applications, apply a minimum of 20 gallons of spray volume per acre. For aerial application, apply a minimum of 5 gallons per acre. Do not apply more than 9 applications of CY MANCO 4-40 Fungicide per year. Do not apply more than 32.5 lbs. of product/A per year. Do not apply to exposed bulb. Do not allow spray or drift to contact bulbs after lifting from soil. Restricted Entry Interval (REI): 12 hours. 				
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13. Within the use for "Tomatoes" revise your table to add "Specific Use Instructions" as a major heading as well as the other headings for this use. You have to add the regions and their respective rates for "West of the Mississippi River" and East of the Mississippi River.

Crop	Diseases	Rate CY MANCO 4-40 Fungicide (lb/acre/application)	Specific Use Instructions	Pre- Harvest Interval (PHI) Days
Tomatoes (not for use on tomatoes in the state of California)	Anthracnose Early blight Gray leaf spot Late blight Leaf mold Septoria leaf spot Bacterial speck	X lbs. – X lbs. West of the Mississippi River X lbs. – X lbs. East of the Mississippi River	Apply at 5-7 day interval. Five (5) days if disease is present or conditions are favorable for disease development.	3 days
Restrictions: <ul style="list-style-type: none"> Do not apply more than 6 applications of CY MANCO 4-40 Fungicide per year. Do not apply more than 21 lbs. of product/A per year. Restricted Entry Interval (REI): 12 hours. 				

14. Revise the "Storage and Disposal" section by deleting the phrase "Spills". Please add the directions from the "Spills" section as the last sentence under the "Pesticide Storage" section.

From: Gibson, Tamue

Sent: Friday, November 14, 2014 1:11 PM

To: 'Don O'Shaughnessy'

Subject: Proposed Product: CY MANCO 4-40 WDG Fungicide: Detailed Label Deficiencies Per Phone Discussion on 11/13/2014:

Hello Dr. O'Shaughnessy. I wanted to follow up with you from my telephone conversation with you on yesterday that your product has substantive labeling deficiencies. Upon completion of the revisions, please email them to me ASAP. As stated on yesterday, **we will need to renegotiate the PRIA date to January 15, 2015.** Please provide your acceptance of the revised PRIA date on company letter head with the administrative information (File Symbol No. 90332-E, OPP Decision Number D-486410, Label Deficiencies). Please email this document by close of business today.

Recommendation of Division Directors Negotiated Due Dates					
Decision #: 486410		Registration #: 90332-E		Petition #: N/A	
<input type="checkbox"/> See page 2 for additional registration entries					
Chemical Name: Mancozeb + Cymoxanil					
Fee Category: R310				PRIA Decision Time Frame: 7 months	
Submitted by: Tamue		Gibson		Branch: OCSPP/OPP/RD	Date: 11/19/2014
Company: Zenith Crop Sciences, S.A					
Original PRIA Due Date: 08/21/2014			Proposed New PRIA Due Date: 01/15/2015		
Previous Negotiated Due Dates: 11/21/2014					
Is the "Fix" in-house?		<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> n/a		If not, date "Fix" expected:	
Negotiated Due Date Reason:					
Additional Data Required	<input type="checkbox"/> Product Chemistry	<input type="checkbox"/> Toxicology	<input type="checkbox"/> Acute Tox	<input type="checkbox"/> Environmental	
	<input type="checkbox"/> Efficacy	<input type="checkbox"/> Ecological	<input type="checkbox"/> Residue	<input type="checkbox"/> Other	
Data Deficiencies	<input type="checkbox"/> Product Chemistry	<input type="checkbox"/> Acute Tox	<input type="checkbox"/> Efficacy	<input type="checkbox"/> Residue	<input type="checkbox"/> Toxicology
	<input type="checkbox"/> Environmental	<input type="checkbox"/> Ecological	<input checked="" type="checkbox"/> Labeling	<input type="checkbox"/> Other	<input type="checkbox"/> Not Submitted
Late Risk Assessment	<input type="checkbox"/> Human Health	<input type="checkbox"/> Ecological			
Interim Consideration	<input type="checkbox"/> Agency Initiated		<input type="checkbox"/> Registrant Initiated		
<input type="checkbox"/> CSF	<input type="checkbox"/> Public Process	<input type="checkbox"/> Risk Issues Environmental	<input type="checkbox"/> Risk Issues Human Health		
<input type="checkbox"/> Impurities Review	<input type="checkbox"/> Label	<input type="checkbox"/> Administrative-FR Notice	<input type="checkbox"/> Other – Comment Field		
Summary of Deficiency Type(s): <input type="checkbox"/> Not Submitted (N) <input type="checkbox"/> Deficiencies (D)					
Product Chemistry: <input type="checkbox"/> Acute Tox: <input type="checkbox"/> Efficacy: <input type="checkbox"/> Labeling: <input checked="" type="checkbox"/> Ecological Data: <input type="checkbox"/> Other (describe): <input type="checkbox"/>					
Describe Interactions with Company (describe when contacted and company's response including response to previous negotiated due dates):					
On 11/13/14, Tamue Gibson contacted Dr. O' Shaughnessy (Agent to Zenith Crop Sciences, S.A.) via email and telephone to discuss the need to renegotiate the PRIA action. The agent agreed to the 60-day renegotiation date.					
"75 Day" Letter sent? <input checked="" type="checkbox"/> Yes, Date sent 11/14/2014 <input type="checkbox"/> No and reason for none? Add comments on page 2					
Rationale for Proposed Due Date: Refer to comment on page 2.					
Registrant notified that this is the last negotiation? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> Not Applicable					
Approve: <input checked="" type="checkbox"/>			Disapprove: <input type="checkbox"/>		
If disapproved, action to be taken:					
OD or DOD Signature: CN=Marty Monell/OU=DC/O=USEPA/C=US				Date: 11/24/2014	

Decision #: 945498	Registration #: 90332-E	Petition #: N/A
<p>Issue(s) (describe in detail):</p> <p>On numerous occasions as early as September 16, 2014 and as late as October 23, 2014, the registrant had been notified of several substantive revisions in an effort to reconstruct his product labeling. On November 5, 2014, FB received the registrant's revised product label. On November 13, 2014, the registrant was notified that further revisions were needed to correct the labeling issues. FB will need time to review and complete the labeling and regulatory portion of the review process.</p>		
<p>Comment(s):</p> <p>The new date (1/15/2015) will allow RD time to review the requested outstanding labeling deficiencies and propose any additional revisions to the label.</p>		

Audit Trail for

Recommendation of Division Directors Negotiated Due Dates

PDF Name: PRIAv5.pdf

Form Number: PRIA

Document Identifier: PRIA-14323100537-TG

SUBMITTED on 11/19/2014 at 02:04:04 PM by CN=Tamue Gibson/OU=DC/O=USEPA/C=US

APPROVED on 11/21/2014 at 01:51:03 PM by CN=Cynthia Giles-Parker/OU=DC/O=USEPA/C=US

APPROVED on 11/21/2014 at 04:07:56 PM by CN=Susan Lewis/OU=DC/O=USEPA/C=US

APPROVED AND COMPLETED on 11/24/2014 at 07:08:00 AM by CN=Marty Monell/OU=DC/O=USEPA/C=US

5: 961956

Gibson, Tamue

From: Don O'Shaughnessy <doctox@mac.com>
Sent: Monday, November 17, 2014 3:13 PM
To: Gibson, Tamue
Subject: Re: Proposed Product: CY MANCO 4-40 WDG Fungicide: Detailed Label Deficiencies Per Phone Discussion on 11/13/2014:
Attachments: cymanco440draftNov.17-14.pdf; ATT00001.htm

Thank you for all your hard work on this, it is much appreciated.

I think I have captured all of this.

For onions, cymoxanil (Tanos label) was the rate limiting component. For tomatoes, again, it was cymoxanil (Curzate) with no east / west difference, so I did not bother doing an east west divide. I did not understand your point about the storage / disposal section. It looks like it was already OK.

Gibson, Tamue

From: Don O'Shaughnessy <doctox@mac.com>
Sent: Friday, November 14, 2014 2:51 PM
To: Gibson, Tamue; Johnson, Hope
Subject: Re: Proposed Product: CY MANCO 4-40 WDG Fungicide: Detailed Label Deficiencies Per Phone Discussion on 11/13/2014:

Thank you for the follow up. You folks do a great job and I hope you know it's appreciated.

3 responses:

1. New PRIA date in letter attached
2. I will get the revised label done ASAP. I said Tuesday but will more likely get done Monday.
3. My name is just "Don"

Don O'Shaughnessy, Ph.D., DABT, DABFM

President, DOC Inc.

427 Hide Away Circle

Cub Run KY 42729

270-524-5633 cell 270-537-5139

doctox@mac.com

www.regtox.net

On Nov 14, 2014, at 12:11 PM, Gibson, Tamue <Gibson.Tamue@epa.gov> wrote:

Hello Dr. O'Shaughnessy. I wanted to follow up with you from my telephone conversation with you on yesterday that your product has substantive labeling deficiencies. Upon completion of the revisions, please email them to me ASAP. As stated on yesterday, **we will need to renegotiate the PRIA date to January 15, 2015.** Please provide your acceptance of the revised PRIA date on company letter head with the administrative information (File Symbol No. 90332-E, OPP Decision Number D-486410, Label Deficiencies). Please email this document by close of business today.

Dr. O'Shaughnessy, we are asking this time frame to ensure we have adequate time to revise your product labeling. We do not anticipate utilizing the entire time frame. However, we will like to complete the registration as soon as possible. I will be emailing you a pdf copy of the Agency 75-Day deficiency letter very shortly. You may contact me at (703) 305-9096 if you would like to discuss your deficiencies in greater detail.

The label deficiencies identified in the Agency's review at this time are:

1. Revise the 3rd bullet within the "First Aid" statement for "If Swallowed" to read "Do not induce vomiting unless told to by a poison control center or doctor."

2. Revise the 4th bullet within the "First Aid" statement for "If Swallowed" to read "Do not give anything to an unconscious person."
3. Revise the 1st bullet within the "First Aid" statement for "If in Eyes" to read "Hold eye open and rinse slowly and gently with water for 15 to 20 minutes."
4. Revise the 2nd bullet within the "First Aid" statement for "If in Eyes" to read "Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye."
5. Revise the heading for the "Precautionary Statements" to the following:

**"PRECAUTIONARY STATEMENTS
 HAZARDS TO HUMANS AND DOMESTIC ANIMALS
 CAUTION"**

6. Revise the last sentence within the precaution statements to read "Remove and wash contaminated clothing before reuse."
7. After the last statement within the "(PPE)" section "See engineering controls for additional requirements", add the following statement: "In addition, for aerial application of CY MANCO 4-40 FUNGICIDE on lettuce (leaf and head), occupational handlers performing mixing / loading operations must wear a particulate respirator with an N, R, P or HE filter NIOSH approval prefix TC-84A."
8. Revise the 2nd bullet within the "User Safety Recommendations" section to read "Remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing."
9. Delete the 2nd sentence "Read all Directions for Use carefully before applying." within the "Directions for Use" section.
10. Revise the following sentence within the "Agricultural Use Requirements" box "Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 24 hours." to read "Do not enter or allow worker entry into treated areas during the restricted entry interval (REI). The REI for each crop is located within the use directions for each crop."
11. Place the heading "PRODUCT INFORMATION" after the "Agricultural Use Requirements" box. After the "PRODUCT INFORMATION" heading add the required paragraphs:

Read all Directions For Use carefully before applying.

Apply as a spray with ground, or air equipment using specified amounts of water to obtain through coverage to plants. Use only commercial or farm plantings. Not for use in residential plantings, or once any commercial crop is turned into U-pick, Pick Your Own or similar operation.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

CERTIFIED MAIL

November 14, 2014

OPP Decision Number: D-486410

D. O' Shaughnessy Consulting, Inc.
Zenith Crop Sciences, S.A.
427 Hide Away Circle
Cub Run, KY 42729

Subject: 75-Day Deficiency Letter
Product Name: CY MANCO 4-40 WDG Fungicide
EPA File Symbol: 90332-E
Application Date: December 27, 2013
EPA Receipt Date: December 30, 2013

Dear Dr. O'Shaughnessy:

The Agency has received and begun its in-depth review of the subject application and has determined that it is incomplete or that further information is needed. This letter is a written notification of those deficiencies and identifies your options under 40 CFR 152.105 and Section 33 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended by the Pesticide Registration Improvement Extension Act (PRIA 3). Your options under 40 CFR 152.105 and section 33 of FIFRA are addressed separately because each involves a different timeframe and set of options for responding to this letter. Please ensure that you consider each of the sections below in determining how and when you respond to this letter.

40 CFR 152.105:

As previously described by telephone dated November 13, 2014, pursuant to 40 CFR 152.105, you are allowed 75 days from the date of this letter ending **January 27, 2015** to provide a response concerning the deficiencies listed in this letter. Your response may include making corrections or additions to complete the application, or notifying the Agency of the date on which you expect to complete the application, or withdrawing your application. If you do not respond to this letter within 75 days or if you respond with a date on which you expect to complete the application but fail to meet that scheduled date, the Agency will treat the application as if you had withdrawn it.

Withdrawal concludes the Agency's review of your application. Any subsequent submission of the same application must then be submitted as a new application with a new deadline for EPA to make a determination on your application and subject to a new registration service fee.

The label deficiencies identified in the Agency's review at this time are:

1. Revise the 3rd bullet within the "First Aid" statement for "If Swallowed" to read "Do not induce vomiting unless told to by a poison control center or doctor."
2. Revise the 4th bullet within the "First Aid" statement for "If Swallowed" to read as "Do not give anything to an unconscious person."
3. Revise the 1st bullet within the "First Aid" statement for "If in Eyes" to read "Hold eye open and rinse slowly and gently with water for 15 to 20 minutes."
4. Revise the 2nd bullet within the "First Aid" statement for "If in Eyes" to read "Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye."
5. Revise the heading for the "Precautionary Statements" to the following:

"PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
CAUTION"

6. Revise the last sentence within the precaution statements to read "Remove and wash contaminated clothing before reuse."
7. After the last statement within the "(PPE)" section "See engineering controls for additional requirements", add the following statement: "In addition, for aerial application of CY MANCO 4-40 FUNGICIDE on lettuce (leaf and head), occupational handlers performing mixing / loading operations must wear a particulate respirator with an N, R, P or HE filter NIOSH approval prefix TC-84A."
8. Revise the 2nd bullet within the "User Safety Recommendations" section to read "Remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing."
9. Delete the 2nd sentence "Read all Directions for Use carefully before applying." within the "Directions for Use" section.
10. Revise the following sentence within the "Agricultural Use Requirements" box "Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 24 hours." to read "Do not enter or allow worker entry into

treated areas during the restricted entry interval (REI). The REI for each crop is located within the use directions for each crop."

11. Place the heading "PRODUCT INFORMATION" after the "Agricultural Use Requirements" box. After the "PRODUCT INFORMATION" heading add the required paragraphs:

Read all Directions for Use carefully before applying.

Apply as a spray with ground, or air equipment using specified amounts of water to obtain through coverage to plants. Use only commercial or farm plantings. Not for use in residential plantings, or once any commercial crop is turned into U-pick, Pick Your Own or similar operation.

For ground application, apply a minimum of 20 gallons of water per acre, increasing the spray volume as the plants mature to ensure through coverage of plant foliage.

For air assisted ground application, apply a minimum of 10 gallons of water per acre.

For aerial application, apply a minimum of 2 gallons of water per acre.

On vegetable and field crops, 2 to 3 gallons of spray per acre are generally optimum; orchards and vineyards can be handled with spray volumes of 5 gallons per acre. Some tall or dense foliage crops requiring greater penetration to the lower leaf surface will require higher spray volumes. Do not apply this product in fewer than 5 gallons spray volume per acre in California.

PRODUCT MIXING INSTRUCTIONS

- 1) Fill the spray tank to 1/4 to 1/3 full of water.
- 2) While agitating, add the specified amounts of CY MANCO 4-40 FUNGICIDE to the spray tank.
- 3) Continue agitating until CY MANCO 4-40 FUNGICIDE is fully dispersed, at least 5 minutes.
- 4) Apply CY MANCO 4-40 FUNGICIDE spray mixture within 12 hours of mixing to avoid product degradation.

SPRAY DRIFT MANAGEMENT

A variety of factors including weather conditions (i.e. wind direction, wind speed, temperature, relative humidity) and method of application (i.e. ground, aerial, airblast, chemigation) can influence pesticide drift. The application must evaluate all factors and make appropriate adjustments when applying this product.

WIND SPEEDS

Do not apply at wind speeds greater than 15 miles per hour (mph).

TEMPERATURE INVERSIONS

If applying at wind speeds less than 3 mph, the applicator must determine if a) conditions of temperature inversion exist, or b) stable atmospheric conditions exist at or below nozzle height. Do not make applications into areas of temperature inversions or stable atmospheric conditions.

OTHER STATE AND LOCAL REQUIREMENTS

Applications must follow all state and local pesticide drift requirements regarding application of mancozeb where states have more stringent regulations, they must be observed.

EQUIPEMENT

All aerial and ground application equipment must be properly maintained and calibrated using appropriate carrier or surrogates.

Additional requirements for aerial applicators:

1. The boom length must not exceed 75% of the wing span or 90 % of the rotor blade diameter.
2. Release spray at the lowest height consistent with efficacy and flight safety. Do not release spray at a height greater than 10 feet above the crop canopy unless a greater height is required for aircraft safety.
3. When applications are made with a crosswind, the swath must be displaced down wind. The applicator must compensate for this displacement at the up and downwind edge of the application area by adjusting the path of the aircraft upwind.

Additional requirements for ground boom application:

1. Do not apply with a nozzle height greater than 4 feet above the crop canopy.

Application

Ground

Thorough coverage with foliar sprays generally results in optimum disease control. To achieve satisfactory coverage use proper spray pressure, volume of spray mixture per acre, nozzles (generally hollow cone), disc (generally D-5 to D-7), nozzle spacing, and tractor speed. Consult spray nozzle and accessory catalogues for specific information on proper equipment calibration.

Hand Sprayers

Thoroughly spray plant foliage until runoff.

Aerial

For aerial application of CY MANCO 4-40 FUNGICIDE to lettuce (head and leaf), occupational handlers performing mixing / loading operations must wear a particulate respirator with an N, R, P or HE filter NIOSH approval prefix TC-84A.

A uniform initial spray deposit over the crop canopy generally results in optimum disease control. Each aircraft should be pre-checked for droplet size, uniformity of spray pattern, swath width, and spray volume. During aerial application, human flaggers are prohibited.

Nozzle selection: Hollow cone brass nozzles with a D-series orifice disc and core (whirlplate) are recommended. Nozzles should point straight down or slightly backward.

Swath width: For most field and vegetable crops, swaths just beyond the wingspan of 36 to 40 feet for light aircraft and up to 45 feet for heavier aircraft are suggested. Optimum swath for helicopters is usually 5 to 10 feet beyond normal boom length.

Altitude: For most crops, position the spray boom 5 to 10 feet above the crop canopy.

Flagging: Mark swaths at the end of the field with permanent flags. Measure swaths accurately with a chain or other device except when rows can be accurately counted.

Crop Restrictions

Cucurbits, lettuce (head and leaf), potatoes, and tomatoes may be re-planted anytime after CY MANCO 4-40 FUNGICIDE applications. All other crops cannot be planted until 30 days after CY MANCO 4-40 FUNGICIDE application.

Foliar Applications

Where EDBC Products Used Allow the Same Maximum Poundage of Active Ingredient Per Acre Per Season: If more than one product containing an EDBC active ingredient (maneb, mancozeb, or metiram) is used on a crop during the same growing season and the EDBC products used allow the same maximum amount in pounds of active ingredient per acre per season, then the total pounds active ingredient of all such EDBC products used must not exceed any one of the specified individual EDBC product maximum season pounds of active ingredient allowed per acre.

Where EBDC Products Used Allow Different Maximum Poundage of Active Ingredient Per Acre Per Season: If more than one product containing an EBDC active ingredient is used on a crop during the same growing season and the EBDC products used allow different maximum poundage of active ingredient per acre per season, then the total poundage of all such EBDC products used must not exceed the lowest specified individual EBDC product maximum seasonal poundage of active ingredient allowed per acre.

12. Revise the heading for the "Crop and Rate Table" to read "Crop Use Directions and Rate Table" and list each crop in alphabetical order.
13. Within the "Crop Use Directions and Rate Table" revise the following headings: "Disease" to "Diseases" and "PHI" to "Pre-harvest Interval (PHI) Days".
14. Within the use for "Cucurbit" revise the heading to "Cucurbit Vegetables (not for use on cucurbits in the state of California:)" Add a "Restrictions:" section. Within the restrictions section, add the following restrictions: "For ground applications, apply a minimum of 20 gallons of spray volume per acre. For aerial application, apply a minimum of 5 gallons per acre. Do not apply more than 8 applications of CY MANCO 4-40 Fungicide per year. Do not apply more than 28 lbs. of product/A per year. Restricted Entry Interval (REI): 12 hours".

Crop	Diseases	Rate CY MANCO 4-40 Fungicide (lb/acre/application)	Specific Use Instructions	Pre-Harvest Interval (PHI) Days
Cucurbit Vegetables: (not for use on cucurbits in the state of California) Chayote Chinese Waxgourd Citron melon Cucumber Gherkin Gourd, edible Momordica Spp. Muskmelon Pumpkin Squash, Summer squash, Winter Watermelon	Alternaria leaf Anthracnose Cercospora Leaf spot Downy Mildew Gummy stem Blight scab	3 lbs. – 4.7 lbs.	Begin applications when plants are in the two-leaf stage and repeat at 7 to 10 day interval when conditions are favorable for disease development. Consult State Cooperative Extension Specialist prior to use.	3 days

Melons Cantaloupes Casaba Crenshaw Honeydew Watermelon	Alternaria leaf Anthracnose Downy Mildew Gummy stem Blight Microdochium blight			
Restrictions: <ul style="list-style-type: none"> For ground applications, apply a minimum of 20 gallons of spray volume per acre. For aerial application, apply a minimum of 5 gallons per acre. Do not apply more than 8 applications of CY MANCO 4-40 Fungicide per year. Do not apply more than 28 lbs. of product/A per year. Restricted Entry Interval (REI): 12 hours 				

15. Within the use for "Grapes" add a "Restrictions:" section. Within the restrictions section add the following restrictions: "In California, do not apply after bloom. East of the Rocky Mountains, do not apply more than 32.8 lbs. of product/A per year. For ground applications, apply a minimum of 20 gallons of spray volume per acre. For aerial application, apply a minimum of 5 gallons per acre. Retreatment Interval (REI): 12 hours.

16.

Crop	Diseases	Rate CY MANCO 4-40 Fungicide (lb/acre/application)	Specific Use Instructions	Pre-Harvest Interval (PHI) Days
Grapes (East of the Rocky Mountains only)	Black rot Bunch rot Phomopsis Downy mildew	3.125 lbs.	Apply at 7-10 day intervals when conditions are favorable for disease development	66 days
Restrictions: <ul style="list-style-type: none"> In California, do not apply after bloom. East of the Rocky Mountains, do not apply more than 32.8 lbs. of product/A per year. For ground applications, apply a minimum of 20 gallons of spray volume per acre. For aerial application, apply a minimum of 5 gallons per acre. Restricted Entry Interval (REI): 12 hours. 				

17. Within the use for "Lettuce" add in parentheses "(head and leaf)". Also add the required respirator requirement within the restrictions section (see example below).

Note: For lettuce, occupational handlers performing mixing/loading operations Must wear a particulate respirator with an N, R, P or HE filter NIOSH approval prefix TC-84A. Within the same crop add the species for Downy Mildew (*Bremia lactuca*)."

18. Within the "Crop Use Directions and Rate Table" for "Lettuce (head and leaf)", revise the "Pre-harvest Interval (PHI) Days" to 3 days for head lettuce, 1 day for leaf lettuce and 14 days in the state of California. Also, add the rate restrictions

for the state of California and states other than the state of California. Please see an example revised Crop Use Directions and Rate Table for each crop (below).

Crop	Diseases	Rate CY MANCO 4-40 Fungicide (lb/acre/application)	Specific Use Instructions	Pre-Harvest Interval (PHI) Days
Lettuce (head and leaf)	Downy Mildew (<i>Bremia lactuca</i>)	3 lbs. – 4.7 lbs.	Apply at 7-10 day intervals when conditions are favorable for disease development	3 days for head lettuce 1 day for leaf lettuce 14 days in the state of California
<p>Restrictions: Note: For lettuce, occupational handlers performing mixing/loading operations Must wear a particulate respirator with an N, R, P or HE filter NIOSH approval prefix TC-84A.</p> <ul style="list-style-type: none"> • In California, do not apply more than x lb CY MANCO 4-40 Fungicide (x lb ai) per acre per crop. • In states other than California, do not apply more than x lb CY MANCO 4-40 Fungicide (x lb ai) per acre per crop. • Do not apply more than 2 applications of CY MANCO 4-40 Fungicide per year. • Do not apply more than 28 lbs. of product/A per year. • Do not apply this product with a U-boom device. • Minimum Retreatment Interval: 7 days. • Restricted Reentry Interval (REI): 12 hours. 				

19. Within the use for "Potato" add a "Restrictions:" section. Within the restrictions section add the following restrictions: "Do not apply within 3 days of harvest in Connecticut, Florida, Maine, Massachusetts, New Hampshire, New York, Ohio, Pennsylvania, Vermont, and Wisconsin. Do not apply more than 7 applications of CY MANCO 4-40 Fungicide per year. Do not apply more than 28 lbs. of product/A per year. For ground applications, apply a minimum of 20 gallons of spray volume per acre. For aerial application, apply a minimum of 5 gallons per acre. Restricted Reentry Interval (REI): 12 hours.

Crop	Diseases	Rate CY MANCO 4-40 Fungicide (lb/acre/application)	Specific Use Instructions	Pre-Harvest Interval (PHI) Days
Potato	Late Blight, Early blight, Brown spot	3 lbs.	Apply at 7-14 day interval beginning at crop height of 4- 6 inches. Use the shorter interval if weather conditions favor disease.	14 days
Restrictions:				

- Do not apply within 3 days of harvest in Connecticut, Florida, Maine, Massachusetts, New Hampshire, New York, Ohio, Pennsylvania, Vermont, and Wisconsin.
- Do not apply more than 7 applications of CY MANCO 4-40 Fungicide per year.
- Do not apply more than 28 lbs. of product/A per year.
- For ground applications, apply a minimum of 20 gallons of spray volume per acre.
- For aerial application, apply a minimum of 5 gallons per acre.
- Restricted Entry Interval (REI): 12 hours.

20. Within the use for "Onions (dry bulb); Garlic Shallots" add a "Restrictions:" section. Within the restrictions section add the following restrictions: "For ground applications, apply a minimum of 20 gallons of spray volume per acre. For aerial application, apply a minimum of 5 gallons per acre. Do not exceed X applications per year. Do not to exposed bulb. Do not allow spray or drift to contact bulbs after lifting from soil. Restricted Entry Interval (REI): 12 hours."

Crop	Diseases	Rate CY MANCO 4-40 Fungicide (lb/acre/application)	Specific Use Instructions	Pre-Harvest Interval (PHI) Days
Onions (dry bulb) Garlic Shallots	Botrytis leaf blight Downy mildew Neck rot Purple blotch (not in the state of California) Rust	3.125 lbs. – 3.9 lbs.	Apply at a 7 day interval before disease is expected to appear.	3 days
Restrictions: <ul style="list-style-type: none"> • For ground applications, apply a minimum of 20 gallons of spray volume per acre. • For aerial application, apply a minimum of 5 gallons per acre. • Do not apply more than X applications of CY MANCO 4-40 Fungicide per year. • Do not apply more than X lbs. of product/A per year. • Do not to exposed bulb. • Do not allow spray or drift to contact bulbs after lifting from soil. • Restricted Entry Interval (REI): 12 hours. 				

21. Within the use for "Tomatoes" add a "Restrictions:" section. Within the restrictions section add the following restrictions: "Do not apply more than X applications of CY MANCO 4-40 Fungicide per year. Do not apply more than X lbs. of product/A per year. Restricted Entry Interval (REI): 12 hours."

Crop	Diseases	Rate CY MANCO 4-40 Fungicide (lb/acre/application)	Specific Use Instructions	Pre-Harvest Interval (PHI) Days
Tomatoes (not for use on tomatoes in the state of California)	Anthrachnose Early blight Gray leaf spot Late blight Leaf mold Septoria leaf spot Bacterial speck	X lbs. – X lbs. West of the Mississippi River X lbs. – X lbs. East of the Mississippi River	Apply at 5-7 day interval. Five (5) days if disease is present or conditions are favorable for disease development.	3 days
Restrictions:				

- Do not apply more than X applications of CY MANCO 4-40 Fungicide per year.
- Do not apply more than X lbs. of product/A per year.
- Restricted Entry Interval (REI): 12 hours.

22. Revise the "Storage and Disposal" section by deleting the heading and adding the directions for use for "Spills" as the last sentence under the "Pesticide Storage" section.

Further review of your application and your response to the deficiencies may identify additional deficiencies and you will be so informed.

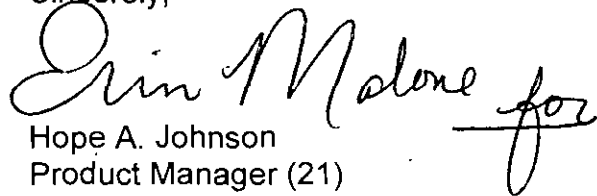
FIFRA Section 33/PRIA:

This application is also subject to a deadline for making a determination on the application under FIFRA Section 33, Pesticide Registration Service Fees, established under PRIA. The time frame for the Agency to make a determination on this application ends on **November 21, 2014**. Because the deadline for the agency to make a determination on this application expires before the end of the 75 days you have to respond to the deficiencies noted above, you have the following three options:

1. **Establish a new due date.** You may work with us to establish a new section 33/PRIA deadline that allows for an appropriate response to the 75 day letter. If you choose this option, you need to contact the Agency not later than **November 21, 2014** to discuss a time frame that allows you to address the deficiencies listed above and the Agency to make a regulatory decision.
2. **Withdraw the application.** Alternatively, you may notify us not later than **November 21, 2014** that you are withdrawing your application. **As noted above, withdrawal concludes the Agency's review** of your application; however, you may resubmit your application after the deficiencies have been addressed. Should you choose to resubmit your application, it would be subject to a new deadline for making a determination on your application and a new registration service fee. Since a fee was paid with this application, the Agency will provide any applicable refund as soon as practicable.
3. **Not respond.** If the Agency does not hear from you by **November 21, 2014**, the Agency in meeting its obligations under section 33/PRIA may issue a determination to not grant your application. While a determination to not grant an application would allow EPA to have met its obligation under section 33 of FIFRA to issue a determination by a specified date, this determination is neither a denial of the application pursuant to section 3(c)(6) of FIFRA or a withdrawal of the application. Thus, the Agency will continue to diligently work on any such application as long as EPA receives a response to a deficiency notice within the 75 days described above.

Please respond to this letter by **November 21, 2014** by contacting Tamue L. Gibson, by telephone number on (703) 305-9096 or by email at Gibson.Tamue@epa.gov or Hope A. Johnson by telephone number on (703) 308-0954 or by email at Johnson.Hope@epa.gov with a response and for any questions concerning this letter. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,

A handwritten signature in cursive script that reads "Erin Malone" followed by a flourish that looks like "for".

Hope A. Johnson
Product Manager (21)
Fungicide Branch
Registration Division (7505P)

Enclosure:

Product Chemistry Review of New End Use Product, DP#: 422647 dated September 22, 2014

From: Gibson, Tamue
Sent: Friday, November 14, 2014 1:11 PM
To: 'Don O'Shaughnessy'
Subject: Proposed Product: CY MANCO 4-40 WDG Fungicide: Detailed Label Deficiencies Per Phone Discussion on 11/13/2014:

Hello Dr. O'Shaughnessy. I wanted to follow up with you from my telephone conversation with you on yesterday that your product has substantive labeling deficiencies. Upon completion of the revisions, please email them to me ASAP. As stated on yesterday, **we will need to renegotiate the PRIA date to January 15, 2015.** Please provide your acceptance of the revised PRIA date on company letter head with the administrative information (File Symbol No. 90332-E, OPP Decision Number D-486410, Label Deficiencies). Please email this document by close of business today.

Dr. O'Shaughnessy, we are asking this time frame to ensure we have adequate time to revise your product labeling. We do not anticipate utilizing the entire time frame. However, we will like to complete the registration as soon as possible. I will be emailing you a pdf copy of the Agency 75-Day deficiency letter very shortly. You may contact me at (703) 305-9096 if you would like to discuss your deficiencies in greater detail.

The label deficiencies identified in the Agency's review at this time are:

1. Revise the 3rd bullet within the "First Aid" statement for "If Swallowed" to read "Do not induce vomiting unless told to by a poison control center or doctor."
2. Revise the 4th bullet within the "First Aid" statement for "If Swallowed" to read "Do not give anything to an unconscious person."
3. Revise the 1st bullet within the "First Aid" statement for "If in Eyes" to read "Hold eye open and rinse slowly and gently with water for 15 to 20 minutes."
4. Revise the 2nd bullet within the "First Aid" statement for "If in Eyes" to read "Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye."
5. Revise the heading for the "Precautionary Statements" to the following:

"PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
CAUTION"

6. Revise the last sentence within the precaution statements to read "Remove and wash contaminated clothing before reuse."
7. After the last statement within the "(PPE)" section "See engineering controls for additional requirements", add the following statement: "In addition, for aerial application of CY MANCO 4-40 FUNGICIDE on lettuce (leaf and head), occupational handlers performing mixing / loading operations must wear a particulate respirator with an N, R, P or HE filter NIOSH approval prefix TC-84A."

8. Revise the 2nd bullet within the "User Safety Recommendations" section to read "Remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing."
9. Delete the 2nd sentence "Read all Directions for Use carefully before applying." within the "Directions for Use" section.
10. Revise the following sentence within the "Agricultural Use Requirements" box "Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 24 hours." to read "Do not enter or allow worker entry into treated areas during the restricted entry interval (REI). The REI for each crop is located within the use directions for each crop."
11. Place the heading "PRODUCT INFORMATION" after the "Agricultural Use Requirements" box. After the "PRODUCT INFORMATION" heading add the required paragraphs:

Read all Directions For Use carefully before applying.

Apply as a spray with ground, or air equipment using specified amounts of water to obtain through coverage to plants. Use only commercial or farm plantings. Not for use in residential plantings, or once any commercial crop is turned into U-pick, Pick Your Own or similar operation.

For ground application, apply a minimum of 20 gallons of water per acre, increasing the spray volume as the plants mature to ensure through coverage of plant foliage.

For air assisted ground application, apply a minimum of 10 gallons of water per acre.

For aerial application, apply a minimum of 2 gallons of water per acre.

On vegetable and field crops, 2 to 3 gallons of spray per acre are generally optimum; orchards and vineyards can be handled with spray volumes of 5 gallons per acre. Some tall or dense foliage crops requiring greater penetration to the lower leaf surface will require higher spray volumes. Do not apply this product in fewer than 5 gallons spray volume per acre in California.

PRODUCT MIXING INSTRUCTIONS

- 1) Fill the spray tank to 1/4 to 1/3 full of water.
- 2) While agitating, add the specified amounts of CY MANCO 4-40 FUNGICIDE to the spray tank.
- 3) Continue agitating until CY MANCO 4-40 FUNGICIDE is fully dispersed, at least 5 minutes.
- 4) Apply CY MANCO 4-40 FUNGICIDE spray mixture within 12 hours of mixing to avoid product degradation.

SPRAY DRIFT MANAGEMENT

A variety of factors including weather conditions (i.e. wind direction, wind speed, temperature, relative humidity) and method of application (i.e. ground, aerial, airblast, chemigation) can influence pesticide drift. The application must evaluate all factors and make appropriate adjustments when applying this product.

WIND SPEEDS

Do not apply at wind speeds greater than 15 miles per hour (mph).

TEMPERATURE INVERSIONS

If applying at wind speeds less than 3 mph, the applicator must determine if a) conditions of temperature inversion exist, or b) stable atmospheric conditions exist at or below nozzle height. Do not make applications into areas of temperature inversions or stable atmospheric conditions.

OTHER STATE AND LOCAL REQUIREMENTS

Applications must follow all state and local pesticide drift requirements regarding application of mancozeb where states have more stringent regulations, they must be observed.

EQUIPEMENT

All aerial and ground application equipment must be properly maintained and calibrated using appropriate carrier or surrogates.

Additional requirements for aerial applicators:

1. The boom length must not exceed 75% of the wing span or 90 % of the rotor blade diameter.
2. Release spray at the lowest height consistent with efficacy and flight safety. Do not release spray at a height greater than 10 feet above the crop canopy unless a greater height is required for aircraft safety.
3. When applications are made with a crosswind, the swath must be displaced down wind. The applicator must compensate for this displacement at the up and downwind edge of the application area by adjusting the path of the aircraft upwind.

Additional requirements for ground boom application:

1. Do not apply with a nozzle height greater than 4 feet above the crop canopy.

Application

Ground

Thorough coverage with foliar sprays generally results in optimum disease control. To achieve satisfactory coverage use proper spray pressure, volume of spray mixture per acre, nozzles (generally hollow cone), disc (generally D-5 to D-7), nozzle spacing, and tractor speed. Consult spray nozzle and accessory catalogues for specific information on proper equipment calibration.

Hand Sprayers

Thoroughly spray plant foliage until runoff.

Aerial

For aerial application of CY MANCO 4-40 FUNGICIDE to lettuce (head and leaf), occupational handlers performing mixing / loading operations must wear a particulate respirator with an N, R, P or HE filter NIOSH approval prefix TC-84A.

A uniform initial spray deposit over the crop canopy generally results in optimum disease control. Each aircraft should be pre-checked for droplet size, uniformity of spray pattern, swath width, and spray volume. During aerial application, human flaggers are prohibited.

Nozzle selection: Hollow cone brass nozzles with a D-series orifice disc and core (whirlplate) are recommended. Nozzles should point straight down or slightly backward.

Swath width: For most field and vegetable crops, swaths just beyond the wingspan of 36 to 40 feet for light aircraft and up to 45 feet for heavier aircraft are suggested. Optimum swath for helicopters is usually 5 to 10 feet beyond normal boom length.

Altitude: For most crops, position the spray boom 5 to 10 feet above the crop canopy.

Flagging: Mark swaths at the end of the field with permanent flags. Measure swaths accurately with a chain or other device except when rows can be accurately counted.

Crop Restrictions

Cucurbits, lettuce (head and leaf), potatoes, and tomatoes may be re-planted anytime after CY MANCO 4-40 FUNGICIDE applications. All other crops cannot be planted until 30 days after CY MANCO 4-40 FUNGICIDE application.

Foliar Applications

Where EBDC Products Used Allow the Same Maximum Poundage of Active Ingredient Per Acre Per Season: If more than one product containing an EBDC active ingredient (maneb, mancozeb, or metiram) is used on a crop during the same growing season and the EBDC products used allow the same maximum amount in pounds of active ingredient per acre per season, then the total pounds active ingredient of all such EBDC products used must not exceed any one of the specified individual EBDC product maximum season pounds of active ingredient allowed per acre.

Where EBDC Products Used Allow Different Maximum Poundage of Active Ingredient Per Acre Per Season: If more than one product containing an EBDC active ingredient is used on a crop during the same growing season and the EBDC products used allow different maximum poundage of active ingredient per acre per season, then the total poundage of all such EBDC products used must not exceed the lowest specified individual EBDC product maximum seasonal poundage of active ingredient allowed per acre.

12. Revise the heading for the "Crop and Rate Table" to read "Crop Use Directions and Rate Table" and list each crop in alphabetical order.

13. Within the "Crop Use Directions and Rate Table" revise the following headings:
 "Disease" to "Diseases" and "PHI" to "Pre-harvest Interval (PHI) Days".

14. Within the use for "Cucurbit" revise the heading to "Cucurbit Vegetables (not for use on cucurbits in the state of California:)" Add a "Restrictions:" section. Within the restrictions section, add the following restrictions: "For ground applications, apply a minimum of 20 gallons of spray volume per acre. For aerial application, apply a minimum of 5 gallons per acre. Do not apply more than 8 applications of CY MANCO 4-40 Fungicide per year. Do not apply more than 28 lbs. of product/A per year. Restricted Entry Interval (REI): 12 hours". **Please see an example revised Crop Use Directions and Rate Table for each crop (below).**

Crop	Diseases	Rate CY MANCO 4-40 Fungicide (lb/acre/application)	Specific Use Instructions	Pre-Harvest Interval (PHI) Days
Cucurbit Vegetables: (not for use on cucurbits in the state of California) Chayote Chinese Waxgourd Citron melon Cucumber Gherkin Gourd, edible Momordica Spp. Muskmelon Pumpkin Squash, Summer squash, Winter Watermelon	Alternaria leaf Anthracnose Cercospora Leaf spot Downy Mildew Gummy stem Blight scab	3 lbs. – 4.7 lbs.	Begin applications when plants are in the two-leaf stage and repeat at 7 to10 day interval when conditions are favorable for disease development. Consult State Cooperative Extension Specialist prior to use.	3 days
Melons Cantaloupes Casaba Crenshaw Honeydew Watermelon	Alternaria leaf Anthracnose Downy Mildew Gummy stem Blight Microdochium blight			
Restrictions: <ul style="list-style-type: none"> • For ground applications, apply a minimum of 20 gallons of spray volume per acre. • For aerial application, apply a minimum of 5 gallons per acre. • Do not apply more than 8 applications of CY MANCO 4-40 Fungicide per year. • Do not apply more than 28 lbs. of product/A per year. • Restricted Entry Interval (REI): 12 hours 				

15. Within the use for "Grapes" add a "Restrictions:" section. Within the restrictions section add the following restrictions: "In California, do not apply after bloom. East of the Rocky Mountains, do not apply more than 32.8 lbs. of product/A per year. For ground applications, apply a minimum

of 20 gallons of spray volume per acre. For aerial application, apply a minimum of 5 gallons per acre. Retreatment Interval (REI): 12 hours.

Crop	Diseases	Rate CY MANCO 4-40 Fungicide (lb/acre/application)	Specific Use Instructions	Pre-Harvest Interval (PHI) Days
Grapes (East of the Rocky Mountains only)	Black rot Bunch rot Phomopsis Downy mildew	3.125 lbs.	Apply at 7-10 day intervals when conditions are favorable for disease development	66 days
Restrictions: <ul style="list-style-type: none"> In California, do not apply after bloom. East of the Rocky Mountains, do not apply more than 32.8 lbs. of product/A per year. For ground applications, apply a minimum of 20 gallons of spray volume per acre. For aerial application, apply a minimum of 5 gallons per acre. Restricted Entry Interval (REI): 12 hours. 				

16. Within the use for "Lettuce" add in parentheses "(head and leaf)". Also add the required respirator requirement within the restrictions section (see example below).

Note: For lettuce, occupational handlers performing mixing/loading operations Must wear a particulate respirator with an N, R, P or HE filter NIOSH approval prefix TC-84A. Within the same crop add the species for Downy Mildew (*Bremia lactuca*)."

17. Within the "Crop Use Directions and Rate Table" for "Lettuce (head and leaf)", revise the "Pre-harvest Interval (PHI) Days" to 3 days for head lettuce, 1 day for leaf lettuce and 14 days in the state of California. Also, add the rate restrictions for the state of California and states other than the state of California. Please see an example revised Crop Use Directions and Rate Table for each crop (below).

Crop	Diseases	Rate CY MANCO 4-40 Fungicide (lb/acre/application)	Specific Use Instructions	Pre-Harvest Interval (PHI) Days
Lettuce (head and leaf)	Downy Mildew (<i>Bremia lactuca</i>)	3 lbs. – 4.7 lbs.	Apply at 7-10 day intervals when conditions are favorable for disease development	3 days for head lettuce 1 day for leaf lettuce 14 days in the state of California
Restrictions: Note: For lettuce, occupational handlers performing mixing/loading operations Must wear a particulate respirator with an N, R, P or HE filter NIOSH approval prefix TC-84A. <ul style="list-style-type: none"> In California, do not apply more than x lb CY MANCO 4-40 Fungicide (x lb ai) per acre per crop. In states other than California, do not apply more than x lb CY MANCO 4-40 Fungicide (x lb ai) per acre per crop. Do not apply more than 2 applications of CY MANCO 4-40 Fungicide per year. Do not apply more than 28 lbs. of product/A per year. Do not apply this product with a U-boom device. Minimum Retreatment Interval: 7 days. Restricted Reentry Interval (REI): 12 hours. 				

18. Within the use for "Potato" add a "Restrictions:" section. Within the restrictions section add the following restrictions: "Do not apply within 3 days of harvest in Connecticut, Florida, Maine, Massachusetts, New Hampshire, New York, Ohio, Pennsylvania, Vermont, and Wisconsin. Do not apply more than 7 applications of CY MANCO 4-40 Fungicide per year. Do not apply more than 28 lbs. of product/A per year. For ground applications, apply a minimum of 20 gallons of spray volume per acre. For aerial application, apply a minimum of 5 gallons per acre. Restricted Reentry Interval (REI): 12 hours.

Crop	Diseases	Rate CY MANCO 4-40 Fungicide (lb/acre/application)	Specific Use Instructions	Pre-Harvest Interval (PHI) Days
Potato	Late Blight, Early blight, Brown spot	3 lbs.	Apply at 7-14 day interval beginning at crop height of 4-6 inches. Use the shorter interval if weather conditions favor disease.	14 days
Restrictions: <ul style="list-style-type: none"> Do not apply within 3 days of harvest in Connecticut, Florida, Maine, Massachusetts, New Hampshire, New York, Ohio, Pennsylvania, Vermont, and Wisconsin. Do not apply more than 7 applications of CY MANCO 4-40 Fungicide per year. Do not apply more than 28 lbs. of product/A per year. For ground applications, apply a minimum of 20 gallons of spray volume per acre. For aerial application, apply a minimum of 5 gallons per acre. Restricted Entry Interval (REI): 12 hours. 				

19. Within the use for "Onions (dry bulb); Garlic Shallots" add a "Restrictions:" section. Within the restrictions section add the following restrictions: "For ground applications, apply a minimum of 20 gallons of spray volume per acre. For aerial application, apply a minimum of 5 gallons per acre. Do not exceed X applications per year. Do not to exposed bulb. Do not allow spray or drift to contact bulbs after lifting from soil. Restricted Entry Interval (REI): 12 hours."

Crop	Diseases	Rate CY MANCO 4-40 Fungicide (lb/acre/application)	Specific Use Instructions	Pre-Harvest Interval (PHI) Days
Onions (dry bulb) Garlic Shallots	Botrytis leaf blight Downy mildew Neck rot Purple blotch (not in the state of California) Rust	3.125 lbs. – 3.9 lbs.	Apply at a 7 day interval before disease is expected to appear.	3 days
Restrictions: <ul style="list-style-type: none"> For ground applications, apply a minimum of 20 gallons of spray volume per acre. For aerial application, apply a minimum of 5 gallons per acre. Do not apply more than X applications of CY MANCO 4-40 Fungicide per year. Do not apply more than X lbs. of product/A per year. Do not to exposed bulb. Do not allow spray or drift to contact bulbs after lifting from soil. Restricted Entry Interval (REI): 12 hours. 				

20. Within the use for "Tomatoes" add a "Restrictions:" section. Within the restrictions section add the following restrictions: "Do not apply more than X applications of CY MANCO 4-40 Fungicide per year. Do not apply more than X lbs. of product/A per year. Restricted Entry Interval (REI): 12 hours.

Crop	Diseases	Rate CY MANCO 4-40 Fungicide (lb/acre/application)	Specific Use Instructions	Pre-Harvest Interval (PHI) Days
Tomatoes (not for use on tomatoes in the state of California)	Anthracnose Early blight Gray leaf spot Late blight Leaf mold Septoria leaf spot Bacterial speck	<u>X</u> lbs. – <u>X</u> lbs. West of the Mississippi River <u>X</u> lbs. – <u>X</u> lbs. East of the Mississippi River	Apply at 5-7 day interval. Five (5) days if disease is present or conditions are favorable for disease development.	3 days
Restrictions: <ul style="list-style-type: none"> Do not apply more than <u>X</u> applications of CY MANCO 4-40 Fungicide per year. Do not apply more than <u>X</u> lbs. of product/A per year. Restricted Entry Interval (REI): 12 hours. 				

21. Revise the "Storage and Disposal" section by deleting the heading and adding the directions for use for "Spills" as the last sentence under the "Pesticide Storage" section.

From: Gibson, Tamue

Sent: Tuesday, August 12, 2014 1:12 PM

To: Don O'Shaughnessy

Subject: Please revise the PRIA date to November 21, 2014: Proposed Product: CY-MANCO 4-40 WDG Fungicide

Dr. O'Shaughnessy. If you would, please revise the renegotiation date within your letter to November 21, 2014. TRB has to have adequate time to review the data/CSF's and FB will need our time to review your entire new registration package.

Thank you.

Tamue

From: Gibson, Tamue

Sent: Tuesday, August 12, 2014 12:00 PM

To: 'Don O'Shaughnessy'

Cc: Johnson, Hope

Subject: RE: Proposed Product: CY-MANCO 4-40 WDG Fungicide

Hello Dr. O'shaughnessy. Just a couple of clarifications. The reference within your letter (2nd to last paragraph) to the enforcement analytical method being included within the storage stability data should be removed. If you intend to submit the enforcement analytical method guideline data(guideline 830.1880) within the pages of the storage stability data the Agency will not continue to work on your PRIA application until this data is submitted separately from the storage stability guideline data. If you do not agree with the Agency's requirement, we will need to set up a conference call with you to discuss this action further and the need to withdraw your PRIA amendment. Please advise.

Also, please refer to the Agency's test guideline data website that are required by registrants. The first link explains why you need this data and the 2nd link provides the details of the requirement to submit the data (in particular product chemistry data).

<http://www.epa.gov/ocspp/pubs/frs/home/guidelin.htm>

http://www.epa.gov/ocspp/pubs/frs/publications/Test_Guidelines/series830.htm.

Thank you.

Tamue L. Gibson, M.S.
U.S. EPA/Registration Division
(703) 305-9096 Voice Mail
Gibson.Tamue@EPA.GOV Email

From: Don O'Shaughnessy [<mailto:doctox@mac.com>]
Sent: Tuesday, August 12, 2014 10:59 AM
To: Gibson, Tamue
Subject: Re: Proposed Product: CY-MANCO 4-40 WDG Fungicide

Secondl last paragraph. If you need different phrasing, please advise and I will whip up a new one.

5:96949

Gibson, Tamue

From: Gibson, Tamue
Sent: Thursday, October 23, 2014 10:36 AM
To: doctox@mac.com
Subject: REQUEST FOR REVISED PRODUCT LABELING: Proposed Product: CY-MANCO 4-40 WDG Fungicide

Hello Dr. O'Shaughnessy, please incorporate the following revisions within your label. My label review is not complete until I receive the correct cited product numbers. In our discussion on yesterday, EPA Reg. Number 352-694 is the not the correct name or reg. no. for Dupont Curzate 60 DF Fungicide. Please provide me guidance as to which labels you want me to review to complete your label assessment. Additionally, please provide a new application form with the updated item #6 "My product is similar or identical in composition and labeling to: ?"

Page 1, delete the word "Draft" from your label.

Page 1, align all decimals exactly under the corresponding decimals for each mancozeb sub-ingredient and "other ingredients" to the active ingredient "Cymonxanil" "4.0 %"

Page 1, add the phrase "Manufactured For" prior to the address of the name of the producer of the product

"Manufactured For
Zenith Crop Sciences, S.A.
Abundt 36, P.O. Box 880
FL 9490 Vaduz, Liechtenstein"

Page 1, within the "First Aid" statement box, revise the precautionary statements as follows:

"If on skin:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

If swallowed:

- Call a poison control center or doctor immediately for treatment advice.
- Have a person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything to an unconscious person.

If in eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- Call a poison control center or doctor for treatment advice."

Page 2, revise the "Precautionary Statements" as follows:

Precautionary Statements

Hazardous to Humans and Domestic Animals

Caution. Harmful if absorbed through skin. Harmful if swallowed. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Wear long-sleeved shirt and long pants, socks, shoes, chemical-resistant gloves (such as Natural Rubber, Selection Category A) and protective eyewear (if appropriate). Remove and wash contaminated clothing before reuse.

Thank you.

Tamue

From: Gibson, Tamue
Sent: Thursday, July 31, 2014 11:52 AM
To: 'doctox@mac.com'
Subject: FW: Proposed Product: CY-MANCO 4-40 WDG Fungicide

Hello Dr. O'Shaughnessy, please let me know if the transmission did not reach you.

Thank you.

From: Gibson, Tamue
Sent: Tuesday, July 29, 2014 3:22 PM
To: 'doctox@mac.com'
Cc: Johnson, Hope
Subject: Proposed Product: CY-MANCO 4-40 WDG Fungicide

Hello Dr. O' Shaughnessy, please send the **revised CSF's and data via front end processing. Also, your PRIA amendment will need to be renegotiated. Please send to me an electronic copy as well as a copy via front end a letter on company correspondence agreeing to a new PRIA date of September 27, 2014. Also, include the Product Name, File Symbol No., Decision No. 418416 within your letter.**

Please note, your product labeling needs revising as well. Please review the acute tox. Review and follow the stated revisions to your product label from the acute tox review. Both acute tox review and product chemistry memo are located within the attachment.

In addition to the revisions stated by the acute tox review, please also revise your label as follows:

Page 1, delete the word "Draft" from your label.

Page 1, align all decimals exactly under the corresponding decimals for each mancozeb sub-ingredient.

Page 1, add the phrase "Manufactured For" prior to the address of the name of the producer of the product

"Manufactured For
Zenith Crop Sciences, S.A.
Abundt 36, P.O. Box 880
FL 9490 Vaduz, Liechtenstein"

Also, please revise your administrative documents to (application form 8570-1; Formulator's Exemption Statement form 8570-27; Certification with Respect to Citation of Data Form 8570-34 and Data Matrix) to the following address:

ZENITH CROP SCIENCES, S.A
c/o D. O'Shaughnessy Consulting, Inc.
427 Hide Away Circle
Cub Run, Kentucky 42729

Within the **application form 8570-1** please revise/include the following:

Item #5 Revise the Applicant's Name and Address to ZENITH CROP SCIENCES, S.A
c/o D. O'Shaughnessy Consulting, Inc. 427 Hide Away Circle Cub Run, Kentucky 42729

Item #2 Product Manager's name: Hope A. Johnson, PM #21

Item #1 Product Number: 9033-E

Item #6 "My Product is Similar or Identical in composition or labeling to:

EPA Reg. No. 352-694

Product Name Dupont Curzate 60DF Fungicide

EPA Reg. No. 352-592

Product Name Curzate 60DF Fungicide

EPA Reg. No. 89333-1

Product Name Furtuna 75 WDG Fungicide

*Product ingredient source information
may be entitled to confidential treatment*

Within the **formulator's exemption statement form 8570-27** please revise/include the following:

Applicant's Name and Address: ZENITH CROP SCIENCES, S.A

c/o D. O'Shaughnessy Consulting, Inc. 427 Hide Away Circle Cub Run, Kentucky 42729

EPA File Symbol No.: 9033-E

Under the "Source", Identify the correct name of each product. Six (6) of the eight (8) products listed are name incorrectly.

Date of Confidential Statement of Formula: Include the new date of the revised CSF's and remember to sign your documents.

Within the **Certification with Respect to Citation of Data EPA Form 8570-34** please revise/include the following:

Applicant's/Registrant's Name, Address and Telephone Number: ZENITH CROP SCIENCES, S.A

c/o D. O'Shaughnessy Consulting, Inc. 427 Hide Away Circle Cub Run, Kentucky 42729, ()
XXX-XXXX,

EPA File Symbol No.: 9033-E

Within the **Data Matrix**, please revise/include the following:

Applicant's/Registrant's Name and Address:

ZENITH CROP SCIENCES, S.A

c/o D. O'Shaughnessy Consulting, Inc.

427 Hide Away Circle Cub Run, Kentucky 42729
EPA Reg. Ho./EPA File Symbol No.: 9033-E

Regards,

Tamue L. Gibson, M.S.
Biologist
U.S. EPA/Registration Division
(703) 305-9096 Voicemail
Gibson.tamue@epa.gov Email


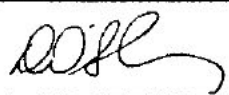
Gibson, Tamue

From: Don O'Shaughnessy <doctox@mac.com>
Sent: Thursday, October 23, 2014 3:30 PM
To: Gibson, Tamue
Subject: Re: REQUEST FOR REVISED PRODUCT LABELING: Proposed Product: CY-MANCO 4-40 WDG Fungicide
Attachments: applicymancoOct23-14.pdf; ATT00001.htm; cymanco440draftOct23-14.pdf; ATT00002.htm; 75WDGstampscanpage1.pdf; ATT00003.htm; mtroyal11.jpeg; ATT00004.htm; lakeplac7.jpeg; ATT00005.htm; yellowred5.jpeg; ATT00006.htm

This should do it ... let me know if not.

On the point of the sub-composition of the mancozeb, the mancozeb-only labels were required to have them inset so as not to be confused as being part of the 100%. I attach a copy of the stamped mancozeb 75 as comparison. I think they should all be consistent, n'est-ce pas?

Also, no reason Ms. Roe should get all the good photos ... How are the fall colors in your neighborhood?

 United States Environmental Protection Agency Washington, DC 20460		<input checked="" type="checkbox"/> Registration <input type="checkbox"/> Amendment <input type="checkbox"/> Other	OPP Identifier Number <div style="font-size: 1.5em;">304921</div>
Application for Pesticide - Section I			
1. Company/Product Number 90332 - E		2. EPA Product Manager Hope Johnson	
4. Company/Product (Name) Zenith Crop Sciences / CY-MANCO 4-40 WDG Fungicide		3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted	
5. Name and Address of Applicant (Include ZIP Code) Zenith Crop Sciences S.A., c/o D. O'Shaughnessy Consulting, Inc., 427 Hide Away Circle, Cub Run, KY 42729 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. 352-604 352-592, 89333-1, [REDACTED] Dupont Tanos Curzate Fortuna 75 WDG Product Name 60 DF Fungicide [REDACTED]	
Section - II			
<input type="checkbox"/> Amendment - Explain below.		<input type="checkbox"/> Final printed labels in response to Agency letter dated _____	
<input type="checkbox"/> Resubmission in response to Agency letter dated _____		<input type="checkbox"/> "Me Too" Application.	
<input type="checkbox"/> Notification - Explain below.		<input checked="" type="checkbox"/> Other - Explain below.	
Explanation: Use additional page(s) if necessary. (For section I and Section II.) Application to register a novel formulation of cymoxanil + mancozeb co-fungicides.			
Section - III			
1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input checked="" type="checkbox"/> Other (Specify) foil lined paper bag
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt. No. per container
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 30 lb, 50 lb	
		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product		<input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled <input type="checkbox"/> Other _____	
Section - IV			
1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Don O'Shaughnessy		Title Agent	
		Telephone No. (Include Area Code) 270-524-5633	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)
2. Signature 		3. Title Agent	
4. Typed Name Don O'Shaughnessy		5. Date 10-05-2013	

CY-MANCO 4 - 40 WDG FUNGICIDE

ACTIVE INGREDIENT:

Mancozeb (a coordination product of zinc ion and manganese ethylenedisithiocarbamate)			40.0 %
manganese++	8.0%		
zinc	1.0%		
ethylenedisithiocarbamate ion	31.0%		
Cymoxanil		4.0 %	
OTHER INGREDIENTS			56 %
TOTAL:			100.0 %

KEEP OUT OF REACH OF CHILDREN

CAUTION

FIRST AID
IF ON SKIN <ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
IF SWALLOWED: <ul style="list-style-type: none"> • Call poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by the poison control center or doctor. • Do not give anything by mouth to an unconscious person.
IF IN EYES: <ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water or 15 to 20 minutes. • Remove contact lenses, if present, after the first minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For information on this pesticide product (including health concerns, medical emergencies or pesticide incidents), call the National Pesticide Information Center at 1-800-858-7378.
This product contains mancozeb and ETU, chemicals known to the State of California to cause cancer. ETU is also known to the State of California to cause birth defects or other reproductive harm.

EPA Reg. No. 90332- E

EPA Est. No. 90332-LIE-1

Net Contents _____

Batch No. _____

Manufactured For:
 Zenith Crop Sciences, S.A.
 Aubundt 36, PO Box 880
 FL 9490 Vaduz, Liechtenstein
 tel. 00359 888 576 735

Product of Bulgaria

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

CAUTION: Harmful if absorbed through skin. Harmful if swallowed. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Wear long-sleeved shirt and long pants, socks, shoes, chemical-resistant gloves (such as Natural Rubber, Selection Category A) and protective eyewear (if appropriate). Remove and wash contaminated clothing before reuse.

Personal Protective Equipment (PPE)

Some materials that are chemical-resistant to this product are nitrile rubber, natural rubber, or butyl rubber. If you want more options, follow the instructions for Category A on an EPA chemical resistance category selection chart.

Mixers, loaders, applicators and other handlers must wear:

- long-sleeved shirt
- long pants
- shoes and socks
- chemical-resistant gloves made of any waterproof material.

See engineering controls for additional requirements.

User Safety Requirements

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry. Discard clothing and other absorbed materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them.

Engineering Controls

Enclosed Cockpits: Pilots must use an enclosed cockpit that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d) (4-6)].

Mechanical Flagging Engineering Controls: Human flagging is prohibited. Flagging to support aerial application is limited to use of the Global Positioning System (GPS) or mechanical flaggers.

User Safety Recommendations

Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.
- Remove clothing/PPE immediately if pesticide gets inside, then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to aquatic organisms. Drift and runoff from treated areas may be hazardous to aquatic organisms in neighboring areas. Do not apply directly to water, or to areas where surface water is present, or to intertidal areas below the mean high water mark. Do not contaminate water when cleaning equipment or disposing of equipment

washwaters or rinsate. For guidance, contact your State Water Board or Regional Office of the Environmental Protection Agency.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Read all Directions for Use carefully before applying.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your state or tribe, consult the agency responsible for pesticide regulation.

Agricultural Use Requirements

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR Part 170. This standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted-entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 24 hours.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, oil or water, is:

- Coveralls
- Chemical-resistant gloves made of any waterproof material
- Shoes plus socks

CROP ROTATION RESTRICTIONS

Potatoes, tomatoes, cucurbit crops, lettuce (head and leafy), peppers, spinach, and hops may be re-planted anytime after CY-MANCO 4-40 FUNGICIDE applications. All other crops cannot be planted until 30 days after CY-MANCO 4-40 FUNGICIDE application.

CROP AND RATE TABLE

Crop	Disease	Rate CY-MANCO 4-40 FUNGICIDE	Specific Instructions / Restrictions	PHI
Lettuce	Downy mildew	3 lb - 4.7 lb product per acre per application	apply at 7- 10 day intervals when conditions are favorable for disease development Maximum application per season is 28 lb product	10 days, 14 days in California
Cucurbits (not for use on cucurbits in California): Chayote Chinese waxgourd Citron melon Cucumber Gherkin gourd Edible Momordica spp. Muskmelon Pumpkin Squash, Summer squash, Winter watermelon	Alternaria leaf spot Anthracnose Cercospora leaf spot Downy mildew Gummy stem blight Scab	3lb - 4.7 lb product per acre per application	apply at 7 - 10 day intervals when conditions are favorable for disease development Maximum application per season is 28 lb product.	3 days
Melons Cantaloupes Casaba crenshaw Honeydew Watermelon	Alternaria leaf spot Anthracnose Downy mildew Gummy stem blight Microdochium blight			

Tomatoes (not for use in California)	Anthracnose Early blight Gray leaf spot Late blight Leaf mold Septoria leaf spot Bacterial speck	3 lb - 4.7 lb product per acre	Apply at 5-7, day intervals, 5 days if disease is present or conditions are favorable for disease development Maximum 28.12 lb product / yr	5 days
Potato	Late blight Early blight, Brown spot	3 lb product	Apply at 7 - 14 day intervals beginning at crop height of 4 - 6 inches Use the shorter interval if weather conditions favor disease. Apply a maximum of 7 times / year	14 days
Onions (dry bulb) Garlic Shallots	Botrytis leaf blight Downy mildew Neck rot Purple blotch (not CA) Rust	3.125 - 3.9 lb product per acre per application	For disease prevention: apply at 7 day intervals before disease is expected to appear Spray in 5 gal / acre min (air) or 20 gal / acre(ground)	7 days

Grapes (east of the Rocky Mountains only)	Black rot Bunch rot Phomopsis Downy mildew	3.125 lbproduct per acre per application	Maximum 32.8 lb product per acre / year Do not allow spray or drift to contact onions after removed from soil	30 days
--	---	---	--	---------

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Store in a cool, dry place and in such a manner as to prevent cross contamination with other pesticides, fertilizers, food or feed. Store in original containers and out of the reach of children, preferably in a locked storage area. Do not store near heat or open flame. Handle an open container in a manner as to prevent spillage.

Spills: If the container is leaking or material is spilled, carefully sweep up and wash exposed area with detergent and water. In spill or leak incidents, keep unauthorized people away.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Disposal: Non-refillable container. Do not re-use or re-fill this container. Completely empty bag into application equipment then offer for recycling if available; or dispose of empty bag in a sanitary landfill.

WARRANTY DISCLAIMER

Zenith Crop Sciences, S.A. warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated on the label when used in strict accordance with the directions, subject to the inherent risks set forth below. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, ZENITH CROP SCIENCES, S.A. MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER EXPRESS OR IMPLIED WARRANTY.

INHERENT RISKS OF USE

It is impossible to eliminate all risks associated with use of this product. Unintended consequences may result because of factors such as use of the product contrary to label instructions, which are beyond the control of Zenith Crop Sciences, S.A. or the Seller. Zenith Crop Sciences, S.A. and the Seller shall not be responsible for any risks caused by the incorporation of this product into an end use product by the Buyer or User. Buyer is solely responsible for any risks created by the end use or uses to which Buyer or a User put this product. All of the foregoing risks shall be assumed by Buyer and User, and Buyer and User agree to hold Zenith Crop Sciences, S.A. and Seller harmless for any claims related to such factors.

LIMITATION OF REMEDIES

To the extent consistent with applicable law, the exclusive remedy for losses or damages resulting from this product (including claims based on contract, negligence, strict liability, or other legal theories), shall be limited to one of the following, at Zenith Crop Sciences, S.A. election:

- (1) Refund of purchase price paid by buyer or user for product bought, or
- (2) Replacement of amount of product used.

In no case shall Zenith Crop Sciences, S.A. be liable for consequential, incidental, or special damages or losses.

The terms of the Warranty Disclaimer above and this Limitation of Remedies cannot be varied by any written or verbal statements or agreements. No employee or sales agent of Zenith Crop Sciences, S.A. or the Seller is authorized to vary or exceed the terms of the Warranty Disclaimer or this Limitation of Remedies in any manner.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

DP BARCODE No.: D422647 REG. No. /File Symbol No. 90332-E PRODUCT NAME: CY- MANCO 4-40
WDG FUNGICIDE PC Code(s): 014504, 129106 Decision No. 486410 Action Code: R310 Food Use:
YES [X]

DATE OUT: 09/22/14

SUBJECT: Product Chemistry Review of New End Use Product
Product Name: CY-MANCO 4-40 WDG FUNGICIDE

FROM: Indira Gairola, Product Chemistry Team
Technical Review Branch / Registration Division (7505P)

TO: Tamue Gibson / Hope Johnson PM 21
Fungicide Branch / Registration Division (7505P)

Company Name: ZENITH CROP SCIENCE, S.A.
Formulation Type (granular solid)

SPM 9/22/14

INTRODUCTION:

As per TRB request registrant has re-submitted revised Basic CSF and alternate formulation CSFs #1 to # 7 all dated 07/28/14 and Enforcement Analytical Method MRID # 489938-01 for series (830.1800) for registration of the new End Use Product CY- MANCO 4-40 WDG FUNGICIDE. All the other product chemistry requirements were satisfied earlier. For details please refer to review by Indira Gairola dated 07/24/14

TRB has been asked to determine the acceptability of the aforementioned product chemistry data and CSF.

SUMMARY OF FINDINGS:

1. Name of Active Ingredient(s): Cymoxanil (4.0%), Mancozeb (40.0%).
2. Titration method was used for analysis of active ingredient Mancozeb,
3. Enforcement Analytical Method (MRID # 489938-01) includes method for Cymoxanil. This method is acceptable.

CONCLUSIONS:

TRB has reviewed revised basic CSF dated 07/28/14 and alternate formulation CSFs #1 to #7 all dated 07/28/14 & Enforcement Analytical Method (MRID # 489938-01) data corresponding to guideline 830.1800 series group A for the proposed subject product "CY-MANCO 4-40 WDG FUNGICIDE" and concluded:

1. The aforementioned CSFs are filled out correctly. Certified limits are calculated correctly. All the CSFs are acceptable.
- 2 Data corresponding to 830.1800 series group A for CY- MANCO 4-40 WDG FUNGICIDE are acceptable.

Gibson, Tamue

From: Gibson, Tamue
Sent: Tuesday, September 16, 2014 5:41 PM
To: Don O'Shaughnessy
Subject: RE: Proposed Product: CY-MANCO 4-40 WDG Fungicide

Dr. O'Shaughnessy. Your alternate CSFs #3 and #5 do not add up to 1, 000 in total weight. Please revise and pdf both alternate CSF's as soon as possible.

Thank you.

Tamue

From: Don O'Shaughnessy [mailto:doctox@mac.com]
Sent: Tuesday, July 29, 2014 6:53 PM
To: Gibson, Tamue
Subject: Re: Proposed Product: CY-MANCO 4-40 WDG Fungicide

Is that all?

Will do.

Don O'Shaughnessy, Ph.D., DABT, DABFM

President, DOC Inc.

427 Hide Away Circle

Cub Run KY 42729

270-524-5633 cell 270-537-5139

doctox@mac.com

www.regtox.net

On Jul 29, 2014, at 2:22 PM, Gibson, Tamue <Gibson.Tamue@epa.gov> wrote:

Hello Dr. O' Shaughnessy, please send the **revised CSF's and data via front end processing. Also, your PRIA amendment will need to be renegotiated. Please send to me an electronic copy as well as a copy via front end a letter on company correspondence agreeing to a new PRIA date of September 27, 2014. Also, include the Product Name, File Symbol No., Decision No. 418416 within your letter.**

Please note, your product labeling needs revising as well. Please review the acute tox. Review and follow the stated revisions to your product label from the acute tox review. Both acute tox review and product chemistry memo are located within the attachment.

In addition to the revisions stated by the acute tox review, please also revise your label as follows:

Page 1, delete the word "Draft" from your label.

Page 1, align all decimals exactly under the corresponding decimals for each mancozeb sub-ingredient.

Page 1, add the phrase "Manufactured For" prior to the address of the name of the producer of the product

"Manufactured For
Zenith Crop Sciences, S.A.
Abundt 36, P.O. Box 880
FL 9490 Vaduz, Liechtenstein"

Also, please revise your administrative documents to (application form 8570-1; Formulator's Exemption Statement form 8570-27; Certification with Respect to Citation of Data Form 8570-34 and Data Matrix) to the following address:

ZENITH CROP SCIENCES, S.A
c/o D. O'Shaughnessy Consulting, Inc.
427 Hide Away Circle
Cub Run, Kentucky 42729

Within the **application form 8570-1** please revise/include the following:

Item #5 Revise the Applicant's Name and Address to ZENITH CROP SCIENCES, S.A
c/o D. O'Shaughnessy Consulting, Inc. 427 Hide Away Circle Cub Run, Kentucky 42729

Item #2 Product Manager's name: Hope A. Johnson, PM #21

Item #1 Product Number: 9033-E

Item #6 "My Product is Similar or Identical in composition or labeling to:
EPA Reg. No. 352-694

Product Name Dupont Curzate 60DF Fungicide

EPA Reg. No. 352-592

Product Name Curzate 60DF Fungicide

EPA Reg. No. 89333-1

Product Name Furduna 75 WDG Fungicide

Within the **formulator's exemption statement form 8570-27** please revise/include the following:

Applicant's Name and Address: ZENITH CROP SCIENCES, S.A
c/o D. O'Shaughnessy Consulting, Inc. 427 Hide Away Circle Cub Run, Kentucky 42729

EPA File Symbol No.: 9033-E

Under the "Source", Identify the correct name of each product. Six (6) of the eight (8) products listed are name incorrectly.

Date of Confidential Statement of Formula: Include the new date of the revised CSF's and remember to sign your documents.

Within the **Certification with Respect to Citation of Data EPA Form 8570-34** please revise/include the following:

Applicant's/Registrant's Name, Address and Telephone Number: ZENITH CROP SCIENCES, S.A

c/o D. O'Shaughnessy Consulting, Inc. 427 Hide Away Circle Cub Run, Kentucky 42729, ()
XXX-XXXX,

EPA File Symbol No.: 9033-E

Within the **Data Matrix**, please revise/include the following:

Applicant's/Registrant's Name and Address:

ZENITH CROP SCIENCES, S.A

c/o D. O'Shaughnessy Consulting, Inc.

427 Hide Away Circle Cub Run, Kentucky 42729

EPA Reg. Ho./EPA File Symbol No.: 9033-E

Regards,

Tamue L. Gibson, M.S.
Biologist
U.S. EPA/Registration Division
(703) 305-9096 Voicemail
Gibson.tamue@epa.gov Email

doc

D. O'Shaughnessy Consulting, Inc.

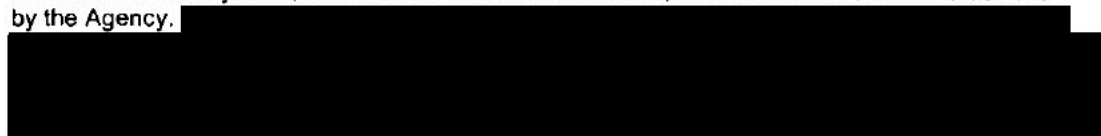
Product ingredient source information may be entitled to confidential treatment

Aug. 13, 2014

Dr. Hope Johnson (PM 22)
US EPA, RD (7504P)
Rm. S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

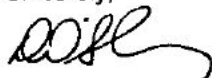
Dear Dr. Johnson,
RE: OPP Decision Number D-486410, File Symbol 90332-E, enforcement analytical method

Per Agency request, enclosed is a DVD with the enforcement analytical method for cymoxanil in formulation (MRID 49448401) plus a revised data matrix to include this study. As noted in the matrix and the study itself, this is a CIPAC standard method, and should be considered as valid by the Agency.

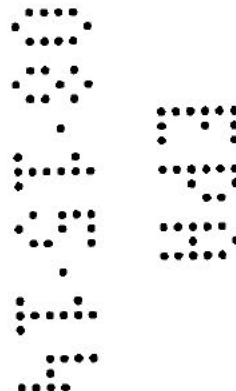


If you have any questions on this submission, please do not hesitate to contact me at the (Kentucky) co-ordinates on this letterhead.

Sincerely,



Don O'Shaughnessy, Ph.D., DABT



427 Hide Away Circle, Cub Run, KY 42729

207 Bank St., Ste. 464, Ottawa, ON CANADA K2P 2N2

Phone 270-524-5633

cell 270-537-5139

email doctox@mac.com

www.regtox.net

Gibson, Tamue

From: Gibson, Tamue
Sent: Tuesday, August 12, 2014 3:24 PM
To: Don O'Shaughnessy
Subject: RE: Proposed Product: CY-MANCO 4-40 WDG Fungicide

Dr. O'Shaughnessy. One quick note of clarification, if you are submitting the data after August 21st, the PRIA negotiation date should be at least 90 days from the date that you submit the data.- Thank you.

From: Don O'Shaughnessy [mailto:doctox@mac.com]
Sent: Tuesday, August 12, 2014 3:03 PM
To: Gibson, Tamue
Subject: Re: Proposed Product: CY-MANCO 4-40 WDG Fungicide

I will prepare a separate document.
Don O'Shaughnessy, Ph.D., DABT, DABFM
President, DOC Inc.
427 Hide Away Circle
Cub Run KY 42729
270-524-5633 cell 270-537-5139
doctox@mac.com
www.regtox.net

On Aug 12, 2014, at 10:59 AM, Gibson, Tamue <Gibson.Tamue@epa.gov> wrote:

Hello Dr. O'shaughnessy. Just a couple of clarifications. The reference within your letter (2nd to last paragraph) to the enforcement analytical method being included within the storage stability data should be removed. If you intend to submit the enforcement analytical method guideline data(guideline 830.1880) within the pages of the storage stability data the Agency will not continue to work on your PRIA application until this data is submitted separately from the storage stability guideline data. If you do not agree with the Agency's requirement, we will need to set up a conference call with you to discuss this action further and the need to withdraw your PRIA amendment. Please advise.

Also, please refer to the Agency's test guideline data website that are required by registrants. The first link explains why you need this data and the 2nd link provides the details of the requirement to submit the data (in particular product chemistry data).

<http://www.epa.gov/ocspp/pubs/frs/home/guidelin.htm>

http://www.epa.gov/ocspp/pubs/frs/publications/Test_Guidelines/series830.htm.

Thank you.

Tamue L. Gibson, M.S.
U.S. EPA/Registration Division
(703) 305-9096 Voice Mail
Gibson.Tamue@EPA.GOV Email

From: Don O'Shaughnessy [mailto:doctox@mac.com]
Sent: Tuesday, August 12, 2014 10:59 AM
To: Gibson, Tamue
Subject: Re: Proposed Product: CY-MANCO 4-40 WDG Fungicide

Secondl last paragraph. If you need different phrasing, please advise and I will whip up a new one.

Gibson, Tamue

From: Gibson, Tamue
Sent: Tuesday, August 12, 2014 1:12 PM
To: Don O'Shaughnessy
Subject: Please revise the PRIA date to November 21, 2014: Proposed Product: CY-MANCO 4-40 WDG Fungicide

Dr. O'Shaughnessy. If you would, please revise the renegotiation date within your letter to November 21, 2014. TRB has to have adequate time to review the data/CSF's and FB will need our time to review your entire new registration package.

Thank you.

Tamue

From: Gibson, Tamue
Sent: Tuesday, August 12, 2014 12:00 PM
To: 'Don O'Shaughnessy'
Cc: Johnson, Hope
Subject: RE: Proposed Product: CY-MANCO 4-40 WDG Fungicide

Hello Dr. O'shaughnessy. Just a couple of clarifications. The reference within your letter (2nd to last paragraph) to the enforcement analytical method being included within the storage stability data should be removed. If you intend to submit the enforcement analytical method guideline data(guideline 830.1880) within the pages of the storage stability data the Agency will not continue to work on your PRIA application until this data is submitted separately from the storage stability guideline data. If you do not agree with the Agency's requirement, we will need to set up a conference call with you to discuss this action further and the need to withdraw your PRIA amendment. Please advise.

Also, please refer to the Agency's test guideline data website that are required by registrants. The first link explains why you need this data and the 2nd link provides the details of the requirement to submit the data (in particular product chemistry data).

<http://www.epa.gov/ocspp/pubs/frs/home/guidelin.htm>

http://www.epa.gov/ocspp/pubs/frs/publications/Test_Guidelines/series830.htm.

Thank you.

Tamue L. Gibson, M.S.
U.S. EPA/Registration Division
(703) 305-9096 Voice Mail
Gibson.Tamue@EPA.GOV Email

From: Don O'Shaughnessy [<mailto:doctox@mac.com>]
Sent: Tuesday, August 12, 2014 10:59 AM
To: Gibson, Tamue
Subject: Re: Proposed Product: CY-MANCO 4-40 WDG Fungicide

Secondl last paragraph. If you need different phrasing, please advise and I will whip up a new one.

Gibson, Tamue

From: Gibson, Tamue
Sent: Tuesday, August 12, 2014 12:00 PM
To: Don O'Shaughnessy
Cc: Johnson, Hope
Subject: RE: Proposed Product: CY-MANCO 4-40 WDG Fungicide

Hello Dr. O'shaughnessy. Just a couple of clarifications. The reference within your letter (2nd to last paragraph) to the enforcement analytical method being included within the storage stability data should be removed. If you intend to submit the enforcement analytical method guideline data(guideline 830.1880) within the pages of the storage stability data the Agency will not continue to work on your PRIA application until this data is submitted separately from the storage stability guideline data. If you do not agree with the Agency's requirement, we will need to set up a conference call with you to discuss this action further and the need to withdraw your PRIA amendment. Please advise.

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Tamue L. Gibson, M.S.
U.S. EPA/Registration Division
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From: Don O'Shaughnessy [mailto:doctox@mac.com]
Sent: Tuesday, August 12, 2014 10:59 AM
To: Gibson, Tamue
Subject: Re: Proposed Product: CY-MANCO 4-40 WDG Fungicide

Secondl last paragraph. If you need different phrasing, please advise and I will whip up a new one.

Gibson, Tamue

From: Gibson, Tamue
Sent: Friday, August 08, 2014 12:56 PM
To: Don O'Shaughnessy
Subject: RE: Proposed Product: CY-MANCO 4-40 WDG Fungicide

Dr. O'shaughnessy. Could you kindly please send to me a pdf copy of your acceptance letter to extend the PRIA due date. We have to complete the internal signatures prior to the PRIA due date on August 21, 2014. Thank you.

From: Don O'Shaughnessy [mailto:doctox@mac.com]
Sent: Thursday, July 31, 2014 11:54 AM
To: Gibson, Tamue
Subject: Re: Proposed Product: CY-MANCO 4-40 WDG Fungicide

Got it - thanks again.
I'm working on the rest and will try to get it onto a DVD by this afternoon's UPS time.
Don O'Shaughnessy, Ph.D., DABT, DABFM
President, DOC Inc.
427 Hide Away Circle
Cub Run KY 42729
270-524-5633 cell 270-537-5139
doctox@mac.com
www.regtox.net

On Jul 31, 2014, at 10:52 AM, Gibson, Tamue <Gibson.Tamue@epa.gov> wrote:

<[Untitled].pdf>



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

August 4, 2014

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

DON O'SHAUGHNESSY, PH.D
D. O'SHAUGHNESSY CONSULTING, INC
ZENITH CROP SCIENCES, S.A.
427 HIDE AWAY CIRCLE
CUB RUN, KY 42729-

PRODUCT NAME: cY MANCO 4-40 WDG FUNGICIDE
COMPANY NAME: ZENITH CROP SCIENCES, S.A.
OPP IDENTIFICATION NUMBER:
EPA FILE SYMBOL: 90332-E
EPA RECEIPT DATE: 08/01/14

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Registration Division, Risk Management Team 21, at (703) 305-5410.

Sincerely,

A handwritten signature in black ink, appearing to be "J. S. [unclear]".

Front End Processing Staff
Information Services Branch
Information Technology & Resources Management Division

Fee for Service

{955818K~

This package includes the following

☒ New Registration

☐ Amendment

☐ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: ____

for Division

☐ AD

☐ BPPD

☒ RD

Risk Mgr.

21

Receipt No.

S-

955818

EPA File Symbol/Reg. No.

90332-E

Pin-Punch Date:

8/1/2014



This item is NOT subject to FFS action.

Action Code:

Requested:

Granted:

Amount Due: \$ ____

Parent/Child Decisions:

☒ Inert Cleared for Intended Use



Uncleared Inert in Product

Reviewer: S. Hill



V. Santos
5/20/14

Date: 8/4/14

Remarks:

Re-sub ? Return for coding if needed.

e-Submission

 United States Environmental Protection Agency Washington, DC 20460		<input checked="" type="checkbox"/> Registration <input type="checkbox"/> Amendment <input type="checkbox"/> Other	OPP Identifier Number <div style="font-size: 1.5em; font-weight: bold;">304921</div>
Application for Pesticide - Section I			
1. Company/Product Number 90332 - E		2. EPA Product Manager Hope Johnson	
4. Company/Product (Name) Zenith Crop Sciences / CY-MANCO 4-40 WDG Fungicide		3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted	
5. Name and Address of Applicant (Include ZIP Code) Zenith Crop Sciences S.A., c/o D. O'Shaughnessy Consulting, Inc., 427 Hide Away Circle, Cub Run, KY 42729 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. 352-694, 352-592, 89333-1, [REDACTED] Product Name DuPont Curzate 60 DF Fung. Fungicide Fortuna 75 WDG Fungicide	
Section - II			
<input type="checkbox"/> Amendment - Explain below. <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input type="checkbox"/> Notification - Explain below.		<input type="checkbox"/> Final printed labels in response to Agency letter dated _____ <input type="checkbox"/> "Me Too" Application. <input checked="" type="checkbox"/> Other - Explain below.	
Explanation: Use additional page(s) if necessary. (For section I and Section II.) Application to register a novel formulation of cymoxanil + mancozeb co-fungicides.			
Section - III			
1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input checked="" type="checkbox"/> Other (Specify) foil lined paper bag
* Certification must be submitted If "Yes" Unit Packaging wgt. No. per container		If "Yes" Package wgt. No. per container	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 30 lb, 50 lb	
		5. Location of Label Directions <input type="checkbox"/> On Label <input checked="" type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____	
Section - IV			
1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Don O'Shaughnessy		Title Agent	
		Telephone No. (Include Area Code) 270-524-5633	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)
2. Signature 		3. Title Agent	
4. Typed Name Don O'Shaughnessy		5. Date 10-05-2013	

e-Submission

doc
D. O'Shaughnessy Consulting, Inc.

July 31, 2014

Dr. Hope Johnson (PM 22)
US EPA, RD (7504P)
Rm. S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Dear Dr. Johnson,
RE: OPP Decision Number D-486410, File Symbol 90332-E. response to Agency letter of July 28, 2014

Thank you for your letter of July 28, and the diligent work of reviewing this submission so far.

Enclosed is a DVD with corrections as described in the letter, **with the exception** that in fact the enforcement analytical methods were in fact included in the original submission. As noted in the data matrix, these are included in MRID 49214803, Storage Stability and Corrosion Characteristics. If EPA determines that these must be submitted separately, I will extract them from MRID 49214803, although this would appear to be a waste of both Agency time and mine.

We understand this response will require additional review of data and agree to a revised PRIA date of Sept. 27, 2014, as proposed by Tamue Gibson (email of July 29, 2014).

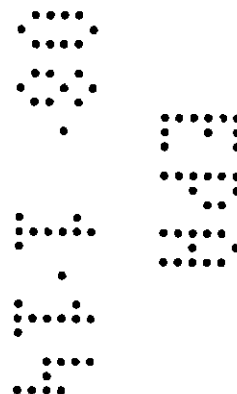
If you have any questions on this submission, please do not hesitate to contact me at the (Kentucky) co-ordinates on this letterhead.

Sincerely,



Don O'Shaughnessy, Ph.D., DABT

e-Submission



427 Hide Away Circle, Cub Run, KY 42729

207 Bank St., Ste. 464, Ottawa, ON CANADA K2P 2N2

Phone 270-524-5633

cell 270-537-5139

email doctox@mac.com

www.regtox.net



United States
Environmental Protection Agency
Washington, DC 20460
Formulator's Exemption Statement
(40 CFR 152.85)

Applicant's Name and Address

Zenith Crop Sciences, S.A.
c/o D. O'Shaughnessy Consulting, Inc.
427 Hide Away Circle
Cub Run, KY 42729

EPA File Symbol/Registration Number

90332-E

Product Name

CY-MANCO 4 - 40 WDG Fungicide

Date of Confidential Statement of Formula (EPA Form 8570-4)

07/28/2014

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s):

mancozeb cymoxanil, mancozeb

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another producer, and is labeled for at least each use for which my product is proposed to be labeled.

(3) Indicate by checking (A) or (B) below which paragraph applies:

☒ (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☐ (B) The Confidential Statement of Formula (CSF) (EPA Form 8570-4) referenced above and on file with the EPA is complete, current, and accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

Source

Active Ingredient	Product Name	Registration Number
cymoxanil		
mancozeb		

Product ingredient source information may be entitled to confidential treatment

Signature

Name and Title

Don O'Shaughnessy, Agent

Date

10-05-2013

e-Submission
White - EPA copy
Yellow - Applicant copy


UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.

WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX


Date revised 07/31/2014			EPA Reg. No./File Symbol 90332-E		Page 1 of 2
Applicant's / Registrant's Name & Address Zenith Crop Sciences, S.A., c/o D. O'Shaughnessy Consulting, Inc., 427 Hide Away Circle, Cub Run, KY 42729			Product CY-MANCO 4 - 40 WDG Fungicide		
Ingredients cymoxanil, mancozeb					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.1550	Product Identity and Composition	(CSF) 49214800	Zenith Crop Sciences	OWN	
830.1600	Description of Materials Used to Produce the Product	49214801	Zenith Crop Sciences	OWN	
830.1620	Description of Manufacturing Process	49214801	Zenith Crop Sciences	OWN	
830.1670	Discussion of Formation of Impurities	49214801	Zenith Crop Sciences	OWN	
830.1750	Certified Limits	(CSF) 49214800	Zenith Crop Sciences	OWN	
830.1800	Enforcement analytical method	49214803	Zenith Crop Sciences	OWN	
830.6303	Physical State	49214802	Zenith Crop Sciences	OWN	
830.6304	Odor	49214802	Zenith Crop Sciences	OWN	
830.6320	Corrosion characteristics	49214802	Zenith Crop Sciences	OWN	
830.7300	Density	49214802	Zenith Crop Sciences	OWN	
830.6302	Color	49214802	Zenith Crop Sciences	OWN	
830.7000	pH	49214802	Zenith Crop Sciences	OWN	
830.6315	Flammability	49214802	Zenith Crop Sciences	OWN	
830.6316	Explosivity	49214802	Zenith Crop Sciences	OWN	
830.6317	Storage stability	49214803	Zenith Crop Sciences	OWN	
Signature 			Name and Title Don O'Shaughnessy, Agent		Date 07/31/2014

e-Submission

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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Date revised 07/31/2014			EPA Reg. No./File Symbol 90332-E		Page 1 of 2
Applicant's / Registrant's Name & Address Zenith Crop Sciences, S.A., c/o D. O'Shaughnessy Consulting, Inc., 427 Hide Away Circle, Cub Run, KY 42729			Product CY-MANCO 4 - 40 WDG Fungicide		
Ingredients cymoxanil, mancozeb					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6320	Corrosion characteristics	49214803	Zenith Crop Sciences	OWN	
830.6314	Oxidation / reduction potential	49214802	Zenith Crop Sciences	OWN	
870.1100	Acute oral toxicity	49214804	Zenith Crop Sciences	OWN	
870.1200	Acute dermal toxicity	49214805	Zenith Crop Sciences	OWN	
870.1300	Acute inhalation toxicity	49214806	Zenith Crop Sciences	OWN	
870.2500	Primary dermal irritation	49214807	Zenith Crop Sciences	OWN	
870.2400	Primary eye irritation	49214808	Zenith Crop Sciences	OWN	
870.2600	Sensitization	492148029	Zenith Crop Sciences	OWN	
Signature 			Name and Title Don O'Shaughnessy, Agent		Date 07/31/2014

DRAFT
CY-COP 6 - 30 WDG FUNGICIDE

ACTIVE INGREDIENT:	
copper hydroxide*	46.1 %
Cymoxanil	6.0 %
OTHER INGREDIENTS	64%
TOTAL:	100.0 %

* 30.0% metallic copper equivalent

KEEP OUT OF REACH OF CHILDREN
CAUTION

FIRST AID
IF SWALLOWED: <ul style="list-style-type: none">• Call poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by the poison control center or doctor.• Do not give anything by mouth to an unconscious person.
IF ON SKIN OR CLOTHING: <ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15 to 20 minutes.• Call a poison control center or doctor for treatment advice.
IF IN EYES: <ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water or 15 to 20 minutes.• Remove contact lenses, if present, after the first minutes, then continue rinsing eye.• Call a poison control center or doctor for treatment advice.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For information on this pesticide product (including health concerns, medical emergencies or pesticide incidents), call the National Pesticide Information Center at 1-800-858-7378.

EPA Reg. No. 90332- x

EPA Est. No. 90332-LIE-1

Net Contents _____

Batch No. _____

Zenith Crop Sciences, S.A.
Aubundt 36, PO Box 880
FL 9490 Vaduz, Liechtenstein
tel. 00359 888 576 735

Product of Bulgaria

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

CAUTION: Causes moderate eye irritation. Prolonged or frequent contact with skin may cause allergic reactions in some individuals. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

Personal Protective Equipment (PPE)

Some materials that are chemical-resistant to this product are nitrile rubber, natural rubber, or butyl rubber. If you want more options, follow the instructions for Category A on an EPA chemical resistance category selection chart.

Mixers, loaders, applicators and other handlers must wear:

- long-sleeved shirt
- long pants
- shoes and socks
- chemical-resistant gloves made of any waterproof material.

See engineering controls for additional requirements.

User Safety Requirements

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry. Discard clothing and other absorbed materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them.

Engineering Controls

Enclosed Cockpits: Pilots must use an enclosed cockpit that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d) (4-6)].

Mechanical Flagging Engineering Controls: Human flagging is prohibited. Flagging to support aerial application is limited to use of the Global Positioning System (GPS) or mechanical flaggers.

User Safety Recommendations

Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.
- Remove clothing/PPE immediately if pesticide gets inside, then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to aquatic organisms. Drift and runoff from treated areas may be hazardous to aquatic organisms in neighboring areas. Do not apply directly to water, or to areas where surface water is present, or to intertidal areas below the mean high water mark. Do not contaminate water when cleaning equipment or disposing of equipment washwaters or rinsate. For guidance, contact your State Water Board or Regional Office of the Environmental Protection Agency.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Read all Directions for Use carefully before applying.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your state or tribe, consult the agency responsible for pesticide regulation.

Agricultural Use Requirements

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR Part 170. This standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted-entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 12 hours.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, oil or water, is:

- Coveralls
- Chemical-resistant gloves made of any waterproof material
- Shoes plus socks

CROP ROTATION RESTRICTIONS

Potatoes, tomatoes, cucurbit crops, lettuce (head and leafy), peppers, spinach, and hops may be re-planted anytime after CY-COP 6-30 FUNGICIDE applications. All other crops cannot be planted until 30 days after CY-COP 6-30 FUNGICIDE application.

CROP AND RATE TABLE

Crop	Disease	Rate CY-COP 6-30 FUNGICIDE	Specific Instructions / Restrictions	PHI
Head and leaf lettuce, Spinach	Downy mildew Ring spot Downy mildew Leaf spot	2 to 3lb product per acre per application Use the 5 lb rate for spinach downy mildew	apply at 5 -7 day intervals when conditions are favorable for disease development Maximum application per season is 18 lb product	3 days for head lettuce, 1 day for leaf lettuce and spinach
Melons and Cucurbits Cucumber Gherkin Muskmelon Cantaloupes Pumpkin Squash, Watermelon	Downy mildew Anthracnose Alternaria Leaf Blight Black rot	2 lb product per acre per application Use the 5 lb rate for spinach downy mildew	apply at 5 -7 day intervals when conditions are favorable for disease development Do not apply more than 4 times per season	3 days
Hops (not for use in California)	Downy mildew	2 lb product per acre per application	apply on a 10 - 14 day schedule Maximum 4 applications per season	7 days
Tomatoes (not for use in California)	Anthracnose Early blight Gray leaf spot Late blight Leaf mold Septoria leaf spot Bacterial speck,	3 lb - 4.7 lb product per acre per application	Apply at 5-7, day intervals, 5 days if disease is present or conditions are favorable for disease development Maximum 28.12 lb product / yr	5 days

Potato	Late blight Early blight	2 lb product per acre per application	Apply at 5 - 7 day intervals beginning at crop height of 3 - 6 inches Use the shorter interval if weather conditions favor disease. Apply a maximum of 7 times / year	14 days
Onions (dry bulb) Garlic Shallots	Botrytis leaf blight Downy mildew (<i>Peronospora destructor</i>) Neck rot Purple blotch (not in California) Rust	2 to 2.5 lb product per acre per application product -	For disease prevention: apply at 5 to 7 day intervals before disease is expected to appear Maximum 32.8 lb product per acre / year Spray in 5 gal / acre min (air) or 20 gal / acre (ground)	3 days Do not allow spray or drift to contact onions after removed from soil.
Grapes (east of the Rocky Mountains only)	Black rot Bunch rot Phomopsis Downy mildew Anthracnose	2lb product per acre per application	apply on a 10 day schedule before disease appearance is expected and continue until fruit set maximum 28 lb / acre / crop cycle Spray in minimum 5 gal / ac by air, or 20 gal / acre minimum with ground equipment. Increase volume as crop matures to ensure good coverage.	30 days

Cane Berries (not in California): Blackberry, Raspberry	Raspberry Leaf spot (Sphaendina rubi) Septoria Leaf spot (Septoria rubi) Spur Blight Downey mildew	2 - 2.5 lb product /acre per application	Apply on a 5 to 7 day schedule before disease appearance is expected For Leafspot, applications should be timed to protect the current season primocanes starting at primocane emergence. Continue fungicide program throughout the period of crop susceptibility. Maximum application per year is 18 lb product.	0 days
Peppers (All varieties of Peppers including pimentos and bell, hot, and sweet peppers)	Anthrachnose (Collectotrichum spp.) Phytophthora blight Cercospora blight Bacterial spot	2 - 2.5 lb product/ acre per application	Apply on a 5 to 7 day schedule before disease appearance is expected. Spray in minimum 5 gal / ac by air, or 20 gal / acre minimum with ground equipment. Maximum application per year is 18 lb product.	3 days

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Store in a cool, dry place and in such a manner as to prevent cross contamination with other pesticides, fertilizers, food or feed. Store in original containers and out of the reach of children, preferably in a locked storage area. Do not store near heat or open flame. Handle an open container in a manner as to prevent spillage.

Spills: If the container is leaking or material is spilled, carefully sweep up and wash exposed area with detergent and water. In spill or leak incidents, keep unauthorized people away.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Disposal: Non-refillable container. Do not re-use or re-fill this container. Completely empty bag into application equipment then offer for recycling if available, or dispose of empty bag in a sanitary landfill.

WARRANTY DISCLAIMER

Zenith Crop Sciences, S.A. warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated on the label when used in strict accordance with the directions, subject to the inherent risks set forth below. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, ZENITH CROP SCIENCES, S.A. MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER EXPRESS OR IMPLIED WARRANTY.

INHERENT RISKS OF USE

It is impossible to eliminate all risks associated with use of this product. Unintended consequences may result because of factors such as use of the product contrary to label instructions, which are beyond the control of Zenith Crop Sciences, S.A. or the Seller. Zenith Crop Sciences, S.A. and the Seller shall not be responsible for any risks caused by the incorporation of this product into an end use product by the Buyer or User. Buyer is solely responsible for any risks created by the end use or uses to which Buyer or a User put this product. All of the foregoing risks shall be assumed by Buyer and User, and Buyer and User agree to hold Zenith Crop Sciences, S.A. and Seller harmless for any claims related to such factors.

LIMITATION OF REMEDIES

To the extent consistent with applicable law, the exclusive remedy for losses or damages resulting from this product (including claims based on contract, negligence, strict liability, or other legal theories), shall be limited to one of the following, at Zenith Crop Sciences, S.A. election:

- (1) Refund of purchase price paid by buyer or user for product bought, or
- (2) Replacement of amount of product used.

In no case shall Zenith Crop Sciences, S.A. be liable for consequential, incidental, or special damages or losses:

The terms of the Warranty Disclaimer above and this Limitation of Remedies cannot be varied by any written or verbal statements or agreements. No employee or sales agent of Zenith Crop Sciences, S.A. or the Seller is authorized to vary or exceed the terms of the Warranty Disclaimer or this Limitation of Remedies in any manner.

Gibson, Tamue

From: Gibson, Tamue
Sent: Thursday, July 31, 2014 11:52 AM
To: doctox@mac.com
Subject: FW: Proposed Product: CY-MANCO 4-40 WDG Fungicide
Attachments: [Untitled].pdf

Hello Dr. O'Shaughnessy, please let me know if the transmission did not reach you.

Thank you.

From: Gibson, Tamue
Sent: Tuesday, July 29, 2014 3:22 PM
To: 'doctox@mac.com'
Cc: Johnson, Hope
Subject: Proposed Product: CY-MANCO 4-40 WDG Fungicide

Hello Dr. O' Shaughnessy, please send the **revised CSF's and data via front end processing. Also, your PRIA amendment will need to be renegotiated. Please send to me an electronic copy as well as a copy via front end a letter on company correspondence agreeing to a new PRIA date of September 27, 2014. Also, include the Product Name, File Symbol No., Decision No. 418416 within your letter.**

Please note, your product labeling needs revising as well. Please review the acute tox. Review and follow the stated revisions to your product label from the acute tox review. Both acute tox review and product chemistry memo are located within the attachment.

In addition to the revisions stated by the acute tox review, please also revise your label as follows:

Page 1, delete the word "Draft" from your label.

Page 1, align all decimals exactly under the corresponding decimals for each mancozeb sub-ingredient.

Page 1, add the phrase "Manufactured For" prior to the address of the name of the producer of the product

"Manufactured For
Zenith Crop Sciences, S.A.
Abundt 36, P.O. Box 880
FL 9490 Vaduz, Liechtenstein"

Also, please revise your administrative documents to (application form 8570-1; Formulator's Exemption Statement form 8570-27; Certification with Respect to Citation of Data Form 8570-34 and Data Matrix) to the following address:

ZENITH CROP SCIENCES, S.A
c/o D. O'Shaughnessy Consulting, Inc.
427 Hide Away Circle
Cub Run, Kentucky 42729

Within the **application form 8570-1** please revise/include the following:

Item #5 Revise the Applicant's Name and Address to ZENITH CROP SCIENCES, S.A
c/o D. O'Shaughnessy Consulting, Inc. 427 Hide Away Circle Cub Run, Kentucky 42729

Item #2 Product Manager's name: Hope A. Johnson, PM #21

Item #1 Product Number: 9033-E

Item #6 "My Product is Similar or Identical in composition or labeling to:

EPA Reg. No. 352-694

Product Name Dupont Curzate 60DF Fungicide

EPA Reg. No. 352-592

Product Name Curzate 60DF Fungicide

EPA Reg. No. 89333-1

Product Name Furtuna 75 WDG Fungicide

*Product ingredient source information
may be entitled to confidential treatment*

Within the **formulator's exemption statement form 8570-27** please revise/include the following:

Applicant's Name and Address: ZENITH CROP SCIENCES, S.A

c/o D. O'Shaughnessy Consulting, Inc. 427 Hide Away Circle Cub Run, Kentucky 42729

EPA File Symbol No.: 9033-E

Under the "Source", Identify the correct name of each product. Six (6) of the eight (8) products listed are name incorrectly.

Date of Confidential Statement of Formula: Include the new date of the revised CSF's and remember to sign your documents.

Within the **Certification with Respect to Citation of Data EPA Form 8570-34** please revise/include the following:

Applicant's/Registrant's Name, Address and Telephone Number: ZENITH CROP SCIENCES, S.A

c/o D. O'Shaughnessy Consulting, Inc. 427 Hide Away Circle Cub Run, Kentucky 42729, ()
XXX-XXXX,

EPA File Symbol No.: 9033-E

Within the **Data Matrix**, please revise/include the following:

Applicant's/Registrant's Name and Address:

ZENITH CROP SCIENCES, S.A

c/o D. O'Shaughnessy Consulting, Inc.

427 Hide Away Circle Cub Run, Kentucky 42729

EPA Reg. Ho./EPA File Symbol No.: 9033-E

Regards,

Gibson, Tamue

From: Gibson, Tamue
Sent: Tuesday, July 29, 2014 3:23 PM
To: doctox@mac.com
Cc: Johnson, Hope
Subject: Proposed Product: CY-MANCO 4-40 WDG Fungicide
Attachments: [Untitled].pdf

Hello Dr. O' Shaughnessy, please send the **revised CSF's and data via front end processing. Also, your PRIA amendment will need to be renegotiated. Please send to me an electronic copy as well as a copy via front end a letter on company correspondence agreeing to a new PRIA date of September 27, 2014. Also, include the Product Name, File Symbol No., Decision No. 418416 within your letter.**

Please note, your product labeling needs revising as well. Please review the acute tox. Review and follow the stated revisions to your product label from the acute tox review. Both acute tox review and product chemistry memo are located within the attachment.

In addition to the revisions stated by the acute tox review, please also revise your label as follows:

Page 1, delete the word "Draft" from your label.

Page 1, align all decimals exactly under the corresponding decimals for each mancozeb sub-ingredient.

Page 1, add the phrase "Manufactured For" prior to the address of the name of the producer of the product

"Manufactured For
Zenith Crop Sciences, S.A.
Abundt 36, P.O. Box 880
FL 9490 Vaduz, Liechtenstein"

Also, please revise your administrative documents to (application form 8570-1; Formulator's Exemption Statement form 8570-27; Certification with Respect to Citation of Data Form 8570-34 and Data Matrix) to the following address:

ZENITH CROP SCIENCES, S.A
c/o D. O'Shaughnessy Consulting, Inc.
427 Hide Away Circle
Cub Run, Kentucky 42729

Within the **application form 8570-1** please revise/include the following:

Item #5 Revise the Applicant's Name and Address to ZENITH CROP SCIENCES, S.A
c/o D. O'Shaughnessy Consulting, Inc. 427 Hide Away Circle Cub Run, Kentucky 42729

Item #2 Product Manager's name: Hope A. Johnson, PM #21

Item #1 Product Number: 9033-E

Item #6 "My Product is Similar or Identical in composition or labeling to:

EPA Reg. No. 352-694

Product Name Dupont Curzate 60DF Fungicide

EPA Reg. No. 352-592

Product Name Curzate 60DF Fungicide

EPA Reg. No. 89333-1

Product Name Furtuna 75 WDG Fungicide

*Product ingredient source information may
be entitled to confidential treatment*

Within the **formulator's exemption statement form 8570-27** please revise/include the following:

Applicant's Name and Address: ZENITH CROP SCIENCES, S.A

c/o D. O'Shaughnessy Consulting, Inc. 427 Hide Away Circle Cub Run, Kentucky 42729

EPA File Symbol No.: 9033-E

Under the "Source", Identify the correct name of each product. Six (6) of the eight (8) products listed are name incorrectly.

Date of Confidential Statement of Formula: Include the new date of the revised CSF's and remember to sign your documents.

Within the **Certification with Respect to Citation of Data EPA Form 8570-34** please revise/include the following:

Applicant's/Registrant's Name, Address and Telephone Number: ZENITH CROP SCIENCES, S.A

c/o D. O'Shaughnessy Consulting, Inc. 427 Hide Away Circle Cub Run, Kentucky 42729, ()
XXX-XXXX,

EPA File Symbol No.: 9033-E

Within the **Data Matrix**, please revise/include the following:

Applicant's/Registrant's Name and Address:

ZENITH CROP SCIENCES, S.A

c/o D. O'Shaughnessy Consulting, Inc.

427 Hide Away Circle Cub Run, Kentucky 42729

EPA Reg. Ho./EPA File Symbol No.: 9033-E

Regards,

Gibson, Tamue

From: Gibson, Tamue
Sent: Monday, July 28, 2014 1:00 PM
To: doctox@mac.com
Subject: Proposed Product: CY-MANCO 4-40 WDG Fungicide

Hello Dr. O' Shaughnessy,

I am the reviewer for your proposed product. I wanted to inform you that your product has been identified as to having product chemistry deficiencies within your application. They are as follows:

1. The data corresponding to 830 series group A for CY-MANCO 4-40 WDG Fungicide are unacceptable. Your basic confidential statement of formula (CSF) dated 9/30/2013 and alternate CSF's #1 to #7 all dated 9/30/2013 are not filled out correctly.
2. Certified limits are not calculated correctly are not in pure active ingredient form within the basic and alternate CSF's #1 to #7 all dated 9/30/2014.
3. The enforcement analytical method (guideline number 830.1880) was not included with your submission and is considered a data gap.

I will be emailing you a pdf copy of the Agency 75-Day Data Deficiency letter very shortly. I will be mailing to you the Agency correspondence as well as the product chemistry and acute toxicology memo for your review.

You may contact me at (703) 305-9096 if you would like to discuss your deficiencies in greater detail.

Regards,

Tamue L. Gibson, M.S.
Biologist
U.S. EPA/Registration Division
(703) 305-9096 Voicemail
Gibson.tamue@epa.gov Email

Gibson, Tamue

From: Don O'Shaughnessy <doctox@mac.com>
Sent: Monday, July 28, 2014 3:42 PM
To: Gibson, Tamue
Subject: Re: Proposed Product: CY-MANCO 4-40 WDG Fungicide
Attachments: cymancoCSFbjuly-14.pdf; ATT00001.htm

Thank you for your observations.

With regard to the enforcement analytical methods, as indicated in the matrix, these are included within the strage stabilty study. If you require I can pull them out and report separately, but this seems a waste of your time and mine.

With regard to the CSFs..... mea culpa, mea culpa. Sed, delibera nos a malo? Bad cutting and pasting. Corrected versions attached.

Do you need these to be submitted in .prz through front end?



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

CERTIFIED MAIL

July 29, 2014

JUL 28 2014

OPP Decision Number: D-486410

D. O' Shaughnessy Consulting, Inc.
Zenith Crop Sciences, S.A.
427 Hide Away Circle
Cub Run, KY 42729

Subject: 75-Day Data Deficiency Letter
Product Name: CY-MANCO 4-40 WDG Fungicide
EPA File Symbol: 90332-E
Application Date: December 27, 2013
EPA Receipt Date: December 30, 2013

Dear Dr. O'Shaughnessy:

The Agency has received and begun its in-depth review of the subject application and has determined that it is incomplete or that further information is needed. This letter is a written notification of those deficiencies and identifies your options under 40 CFR 152.105 and Section 33 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended by the Pesticide Registration Improvement Extension Act (PRIA 3). Your options under 40 CFR 152.105 and section 33 of FIFRA are addressed separately because each involves a different timeframe and set of options for responding to this letter. Please ensure that you consider each of the sections below in determining how and when you respond to this letter.

40 CFR 152.105:

As previously described by e-mail dated July 28, 2014, pursuant to 40 CFR 152.105, you are allowed 75 days from the date of this letter ending **October 14, 2014** to provide a response concerning the deficiencies listed in this letter. Your response may include making corrections or additions to complete the application, or notifying the Agency of the date on which you expect to complete the application, or withdrawing your application. If you do not respond to this letter within 75 days or if you respond with a date on which you expect to complete the application but fail to meet that scheduled

date, the Agency will treat the application as if you had withdrawn it. Withdrawal concludes the Agency's review of your application. Any subsequent submission of the same application must then be submitted as a new application with a new deadline for EPA to make a determination on your application and subject to a new registration service fee.

The deficiencies identified in the Agency's review at this time are:

1. The data corresponding to 830 series group A for CY-MANCO 4-40 WDG Fungicide are unacceptable. Your basic confidential statement of formula (CSF) dated 9/30/2013 and alternate CSF's #1 to #7 all dated 9/30/2013 are not filled out correctly. The certified limits are not calculated correctly.
2. The enforcement analytical method (guideline number 830.1880) was not included with your submission and is considered a data gap.

Further review of your application and your response to the deficiencies may identify additional deficiencies and you will be so informed.

FIFRA Section 33/PRIA:

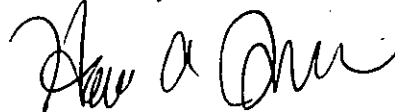
This application is also subject to a deadline for making a determination on the application under FIFRA Section 33, Pesticide Registration Service Fees, established under PRIA. The time frame for the Agency to make a determination on this application ends on **August 21, 2014**. Because the deadline for the agency to make a determination on this application expires before the end of the 75 days you have to respond to the deficiencies noted above, you have the following three options:

1. **Establish a new due date.** You may work with us to establish a new section 33/PRIA deadline that allows for an appropriate response to the 75 day letter. If you choose this option, you need to contact the Agency not later than **August 7, 2014** to discuss a time frame that allows you to address the deficiencies listed above and the Agency to make a regulatory decision.
2. **Withdraw the application.** Alternatively, you may notify us not later than **August 7, 2014** that you are withdrawing your application. **As noted above, withdrawal concludes the Agency's review** of your application; however, you may resubmit your application after the deficiencies have been addressed. Should you choose to resubmit your application, it would be subject to a new deadline for making a determination on your application and a new registration service fee. Since a fee was paid with this application, the Agency will provide any applicable refund as soon as practicable.
3. **Not respond.** If the Agency does not hear from you by **August 7, 2014**, the Agency in meeting its obligations under section 33/PRIA may issue a determination to not grant your application. While a determination to not

grant an application would allow EPA to have met its obligation under section 33 of FIFRA to issue a determination by a specified date, this determination is neither a denial of the application pursuant to section 3(c)(6) of FIFRA or a withdrawal of the application. Thus, the Agency will continue to diligently work on any such application as long as EPA receives a response to a deficiency notice within the 75 days described above.

Please respond to this letter by **August 7, 2014** by contacting Tamue L. Gibson, by telephone number on (703) 305-9096 or by email at Gibson.Tamue@epa.gov or Hope A. Johnson by telephone number on (703) 308-0954 or by email at Johnson.Hope@epa.gov with a response and for any questions concerning this letter. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,



Hope A. Johnson
Product Manager (21)
Fungicide Branch
Registration Division (7505P)

Enclosures:

Product Chemistry Review of New End Use Product, DP#: 418416 dated July 24, 2014
Acute Toxicity Data Evaluation Record (DER) for CY-MANCO 4-40 WDG Fungicide,
DP #: D418416 dated July 1, 2014



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

DP BARCODE No.: D418416 REG. No. /File Symbol No. 90332-E PRODUCT NAME: CY- MANCO 4-40
WDG FUNGICIDE PC Code(s): 014504, 129106 Decision No. 486410 Action Code: R310 Food Use:
YES [X]

DATE OUT: 07/24/14

SUBJECT: Product Chemistry Review of New End Use Product
Product Name: CY-MANCO 4-40 WDG FUNGICIDE

FROM: Indira Gairola, Product Chemistry Team (d) 07/24/14
Technical Review Branch / Registration Division (7505P) S/Bm 7/24/14

TO: Tamue Gibson / Hope Johnson PM 21
Fungicide Branch / Registration Division (7505P)

Company Name: ZENITH CROP SCIENCE, S.A.
Formulation Type:

INTRODUCTION:

The registrant resubmitted an application for registration of the new End Use Product CY- MANCO 4-40 WDG FUNGICIDE". Registrant has submitted Basic CSF and alternate formulation CSFs #1 to # 7 all dated 09/30/13. Applicant is using formulator's exemption and the selective cite all method. Applicant has submitted (MRID #s 492148-01 to -03) for product chemistry data to support this registration application. TRB has been asked to determine the acceptability of the aforementioned product chemistry data and CSF.

SUMMARY OF FINDINGS:

1. Name of Active Ingredient(s) : Cymoxanil (4.0%), Mancozeb (40.0%).
2. Has the registrant claimed substantial similarity to a registered product?
[X] NO [] Yes [] NA; if yes give the registration number of the cited product.
3. All of the source materials of the active ingredient are derived from registered sources-
[X] Yes [] No [] [] Pending registration
4. All inert ingredients have been screened by IIAB and found to be approved for the proposed labeled food uses. [X] YES

5. Confidential Statement of Formula(s):

☒ Proposed Basic and dated 09/30/13. Resubmitted date

☒ Proposed Alternate: 09/30/13. [NA]

Proposed Alternate comply with 40CFR§152.43: ☐ Yes; ☒ No ☐ NA

6. Product label

- a. Ingredient statement: Nominal concentration of AI listed on CSF(s) concurs with product label (PR Notice 91-2)

☒ Yes; ☐ No; if not, explain below:

Is the sub statement in compliance with PR Notice 97-6 (inert ingredient vs. other ingredient?)

☒ Yes; ☐ No; if not, explain below:

Metallic equivalent: ☒ NA
Isomeric ratios ☒ NA
Soluble Arsenic ☒ NA
Acid Equivalent ☒ NA

- b. Health related sub statements: Product contains?

Petroleum distillate at > 10%: ☐ Yes ☒ No ☐ NA

Methanol at > 4%: ☐ Yes ☒ No ☐ NA

Sodium nitrate/Sodium nitrite: ☐ Yes ☒ No ☐ NA

- c. Physical chemical hazard statement: Product label requires a statement per 40 CFR §156.78 for: flammability, explosive potential or electric insulator breakdown?
☐ Yes No ☒

Is the sub statement in compliance with PR Notice 98-6 (Total Release Fogger)?

☐ Yes, ☐ No; ☒ NA; if not, explain below:

- d. Label requires an additional Storage and Disposal statement: ☐ Yes ☒ No; if yes Explain below:

7. Group A: Product Chemistry Data

TRB's determination of the acceptability of the data for the proposed product is listed in the tables below.

Guideline No.	Study Title		Data submitted		TRB's Assessment of Data	MRID Nos.
			Yes	No		
830.1550	Product Identity & Composition		X		N	492148-01 09/30/13Not correctly filled
830.1600	Description of materials used to produce the product		X		A	492148-01
830.1650	Description of formulation process		X		A	492148-01
830.1670	Discussion on the formation of impurities		X			492148-01
830.1700	Preliminary analysis			NA		
830.1750	Certified limits (158.350)	Standard certified Limits	N		N	09/30/13 certified limits are not in pure active ingredient form
		Proposed Limits				
		Justification for wider limits				
830.1800	Enforcement analytical method		N		G	

A = Acceptance, N = Not Acceptable, G = Data Gap,

W = Waiver Request, I = In Progress, NA = Not Applicable, U = Upgradeable.

8. **Group B: BLACK PEARL PASTE**

Guideline No.	Study Title	Value or Qualitative Description	TRB's Assessment of Data	MRID Nos.
830.6303	Physical State	Solid (granular)	A	492148-02
830.6315	Flammability	not flammable	A	492148-02
830.6314	Oxi/ Red	Does not contain any oxidizing or reducing agents	A	492148-02
830.6316	Explodability	not explosive	NA	
830.6320	Corrosion Characteristic	No corrosion expected.	I	492148-03
830.6317	Storage Stability	Stable for 1 year (data in MRID# 492148-03)	AI	492148-03
830.7000	pH	5.01 (1 % soln.) CSF 6.25 (1 % soln.)	A	492148-02
830.7100	Viscosity	NA (solid)		
830.7300	Density (units)	0.61 g/cc, tap 0.61 g/cc	A	492148-02

A = Acceptance, N = Not Acceptable, G = Data Gap, W = Waiver request,
NA = Not applicable, I = In progress, U = Upgradeable.

CONCLUSIONS:

TRB has reviewed submitted basic CSF dated 09/30/13, alternate formulation CSFs #1 to #7 all dated 09/30/13 & data corresponding to guideline 830 series group A & group B for the proposed subject product "CY-MANCO 4-40 WDG FUNGICIDE" and concluded:

1. The data corresponding to 830 series group A for CY- MANCO 4-40 WDG FUNGICIDE are unacceptable. All the above mentioned CSFs are not filled out correctly. Certified limits are not calculated correctly Enforcement. Analytical Method for series (830.1880) is not included. This will be considered as a data gap
2. The data corresponding to 830 series group B for the proposed subject product "CY-MANCO CY- 40 WDG FUNGICIDE" are acceptable.
3. Applicant has submitted data for two weeks at 54°C and for two years at ambient temperature storage stability (guideline 830.6317) and corrosion characteristics guideline (830.6320) observations were made at 0, 3, 6, 9, and 12 month intervals. Results of study report are acceptable. Please refer to the tables attached Table
4. The proposed label was screened as it pertains to the product chemistry requirements.
5. The final review of the proposed label and uses are the purview of the PM team.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

01/JUL/2014

MEMORANDUM: Acute Toxicity Data Evaluation Record (DER) for CY-MANCO 4-40 WDG
FUNGICIDE

Subject: Name of Pesticide Product: CY-MANCO 4-40 WDG FUNGICIDE
EPA File Symbol: 90332-E
DP Barcode: D418416
Decision No.: 486410
Action Code: R310
PC Codes: 014504 Mancozeb
129106 Cymoxanil

From: Tracy Keigwin, Biologist
Technical Review Branch
Registration Division (7505P)

To: Tamue Gibson, RM 21
Fungicide Branch
Registration Division (7505P)

Applicant: Zenith Crop Sciences S.A.
c/o Don O'Shaughnessy
O'Shaughnessy Consulting, Inc.
427 Hide Away Circle
Cub Run, KY 42729

May Keigwin
Y. Haslin
Team Leader / Tox

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>% by wt.</u>
Mancozeb	40.0
Cymoxanil	4.0
<u>Other Ingredient(s):</u>	<u>56.0</u>

Total: 100.0%

ACTION REQUESTED: The Risk Manager requests a review of acute toxicity studies submitted in support of EPA File Symbol 90332-E, CY-MANCO 4-40 WDG FUNGICIDE.

BACKGROUND: Zenith Crop Sciences, S.A. has submitted an application for the registration of EPA File Symbol 90332-E, CY-MANCO 4-40 WDG FUNGICIDE. In support of their application the registrant has submitted the following acute toxicity studies: MRID Nos. 49214804 (870.1100), 49214805 (870.1200), 49214806 (870.1300), 49214808 (870.2400), 49214807 (870.2500) and 49214809 (870.2600). The product label states that CY-MANCO 4-40 WDG FUNGICIDE may be applied to listed agricultural use sites.

GLP: All studies were conducted in accordance with GLP.

DEFICIENCIES/DEVIATIONS: The following deficiencies or deviations were noted:

- 1) The acute LD₅₀ was classified as 5000 mg/kg bw. This is incorrect. The only dose level tested in MRID 49214804 was 2000 mg/kg bw (two groups of 3 tested). No mortality was observed. The acute oral LD₅₀ for this product is >2000 mg/kg bw.
- 2) The acute inhalation toxicity study (MRID 49214806) is classified as supplementary, but may be used for regulatory purposes. Only 3 males and 3 females were tested, however HED Guidelines 870.1300 state that a minimum of 5 males and 5 females should be used. Due to the lack of mortality and clinical signs observed in the test subjects this study may still be used to classify this product as category IV for acute inhalation toxicity.

COMMENTS AND RECOMMENDATIONS:

- 1) Five of the studies are acceptable. The acute inhalation toxicity study (as stated above) is classified as supplementary but still may be used for regulatory purposes.
- 2) The precautionary language and first aid statement are incomplete. Please see the appropriate precautionary statements listed below.
- 3) The Basic CSF and Alternate CSFs 1-7 (all dated September 30, 2013) must be approved by the product chemistry team before this action can be finalized.
- 4) The following are the precautionary and first aid statements for this product, as obtained from the Label Review System:

PRODUCT ID #: 90332-E (90332-2)

PRODUCT NAME: CY-MANCO 4-40 WDG FUNGICIDE

PRECAUTIONARY STATEMENTS

SIGNAL WORD: CAUTION

Hazards to Humans and Domestic Animals:

Harmful if absorbed through skin. Harmful if swallowed. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Wear long-sleeved shirt and long pants, socks, shoes, chemical-resistant gloves (such as Natural Rubber, Selection Category A) and protective eyewear (if appropriate). Remove and wash contaminated clothing before reuse.

First Aid:

If on skin:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

If swallowed:

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything to an unconscious person.

If in eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

USER SAFETY RECOMMENDATIONS:

User should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

User should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

Reviewer: Tracy Keigwin
Risk Manager (EPA): 21

Date: July 1, 2014

The following table is the Acute Toxicity Data Evaluation Record (DER) for the six studies submitted for the proposed product, EPA File Symbol 90332-E:

1. DP BARCODE: 418416				
2. PC CODES: 014504 and 129106				
3. CURRENT DATE: July 1, 2014				
4. TEST MATERIAL: Agria Mancozeb 400 g/kg + Cymoxanil 40 g/kg WDG (Batch number 105MCWG/201205; Purity: 41.92% Mancozeb, 4.20% Cymoxanil; yellowish granules)				
Study/Species/Lab Study # /Date	MRID	Results	Tox Cat	Core Grade
Acute oral toxicity / rat Jai Research Foundation (Gujarat, India) JRF Study Number 401-1-01-5101/ November 12, 2012 OCSPP 870.1100; OECD 423	49214804	LD ₅₀ Females > 2000 mg/kg bw Two sets of females (3 animals per set) tested at 2000 mg/kg bw. All animals survived in each set. No clinical signs observed in either set. No gross abnormalities observed in either set at necropsy Note that the study states that the LD ₅₀ =5000 mg/kg. This is incorrect. The only dose tested was 2000 mg/kg. The LD ₅₀ must be stated as being greater than 2000 mg/kg bw.	III	A
Acute dermal toxicity / rat Jai Research Foundation (Gujarat, India) JRF Study Number 403-1-01-5102/ November 12, 2012 OCSPP 870.1200; OECD 402	49214805	LD ₅₀ > 2000 mg/kg bw (both sexes and combined). No mortality observed in the control group (distilled water application; 5 males and 5 females) or test group (2000 mg/kg test substance application; 5 males and 5 females). No signs of toxicity, dermal irritation or abnormal behavior observed. No gross abnormalities observed at necropsy.	III	A
Acute inhalation toxicity / rat Jai Research Foundation (Gujarat, India) JRF Study Number 405-1-01-5103/ November 19, 2012	49214806	LC ₅₀ > 5.404 mg/L (Nose-only, gravimetric; both sexes (3 males and 3 females) and combined). The MMAD and GSD were 2.87 µm and 2.48,	IV	S

OCSPP 870.1300; OECD 403		<p>respectively. All rats survived. No clinical abnormalities observed. No gross abnormalities observed at necropsy.</p> <p>This study is designated as Supplemental because only 3 males and 3 females were used (HED Guideline 870.1300 states that 5 males and 5 females should be used). It may still be used for regulatory purposes since no mortality or clinical signs were observed in either gender.</p>		
<p>Primary eye irritation / rabbit Jai Research Foundation (Gujarat, India) JRF Study Number 407-1-01-5105/ October 10, 2012 OCSPP 870.2400; OECD 405</p>	49214808	<p>Three animals tested. Control eyes received 0.1 mL 0.9% w/v normal saline. Test eyes received 100 mg of pulverized Agria Mancozeb 400 g/kg + Cymoxanil 40 g/kg WDG. There was no corneal opacity, iritis or conjunctivitis was observed in control eyes. No corneal opacity or iritis was observed in test eyes. Two animals (2/3) exhibited grade 2 redness and chemosis at the one hour observation. All animals (3/3) exhibited grade 2 redness and/or chemosis from the 24 hour observation through the 72 hour observation. All scores were "0" by the day 7 observation.</p>	III	A
<p>Primary dermal irritation / rabbit Jai Research Foundation (Gujarat, India) JRF Study Number 406-1-01-5104/ October 10, 2012 OCSPP 870.2500; OECD 404</p>	49214807	<p>Three animals tested. PDII = 0.42. No erythema or edema observed at control sites (0.5 mL distilled water application). All test sites (500 mg Agria Mancozeb 400 g/kg + Cymoxanil 40 g/kg WDG) exhibited grade 1 erythema at the one hour observation and 2/3 exhibited grade 1</p>	IV	A

		erythema at the 24 hour observation. No edema was observed. All scores were "0" by the 48 hour observation.		
<p>Dermal sensitization / Guinea pig Jai Research Foundation (Gujarat, India) JRF Study Number 408-1-01-5106/ December 04, 2012 OCSP 870.2600; OECD 406</p>	49214809	<p>Not a sensitizer. Tested using Magnusson-Kligman maximization method. 10 test animals and 5 controls.</p> <p><u>Induction intradermal injection (control)</u> – a) 1:1 mixture (v/v) FCA with distilled water; b) distilled water; c) 1:1 (v/v) mixture of injection a) and injection b). <u>Induction intradermal injection (test)</u> – a) 1:1 mixture (v/v) FCA with distilled water; b) 2.5% (w/v) Agria Mancozeb 400 g/kg + Cymoxanil 40 g/kg WDG in distilled water; c) 2.5% (w/v) Agria Mancozeb 400 g/kg + Cymoxanil 40 g/kg WDG formulated in distilled water and 1:1 mixture (v/v) of FCA in distilled water. <u>Induction Topical</u> (Note that 0.5mL 10% (w/v) sodium laurel sulfate in vaseline was applied to test area to augment skin irritation) – 100 mg of Agria Mancozeb 400 g/kg + Cymoxanil 40 g/kg WDG. Control animals received 0.2mL distilled water. <u>Challenge dose</u> – 100 mg of Agria Mancozeb 400 g/kg + Cymoxanil 40 g/kg. Following challenge, no positive dermal irritation was observed in either the 5 control or 10 test animals at 24 or 48 hours. The results of a positive control using α-Hexylcinnamaldehyde were appropriate (JRF study # 408-1-01-4699; 18/JUL/2012).</p>	NO	A

Core Grade Key: A =Acceptable, S = Supplementary, U = Unacceptable, D = Data Gap

Memorandum

Date: 02 / 06 / 2014

E-SUBMISSION

To: PM 22, Regulatory Manager

From: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.

If you have any questions about this process, please contact Teresa Downs (305-5363).

This is a: ☒ fully accepted submission
☐ partially accepted submission
☐ rejected submission



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

January 24, 2014

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

D. O'SHAUGHNESSY CONSULTING, INC
ZENITH CROP SCIENCES, S.A.
427 HIDE AWAY CIRCLE
CUB RUN, KY 42729

Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 30-DEC-13. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 11-03. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

Receipt for Section 3			
S: 945498	Milestone Email:		
Regulatory Type: Product Registration - Section 3	Resubmission: <input type="radio"/> Yes <input checked="" type="radio"/> No	<div>Print Letter</div> <div>Enter More Information</div> <div>Tracking</div>	
Application Type: New Registration	Fee For Service: <input checked="" type="radio"/> Yes <input type="radio"/> No		
Company: 90332 ZENITH CROP SCIENCES, S.A.	Billable: <input checked="" type="radio"/> Yes <input type="radio"/> No		
Risk Manager: Registration Division, Risk Management Team 22			
Product #: 90332-E	Product Name: cY MANCO 4-40 WDG FUNGICIDE		
Override#:			
Me Too Section3:	Me Too Product Name:		
Application Date: 27-Dec-2013	OPP Rec'd Date: 30-Dec-2013	<div>Receipt Content</div> <div>Study</div> <div>CSF</div> <div>View/Edit</div>	
Front End Date: 30-Dec-2013	Risk Manager Send Date: 02-Jan-2014		
FFS Due Date: 21-Aug-2014	Negotiated Due Date:		
OPP Target Date:			
Fast Track: <input type="checkbox"/>	New Ingredient: <input type="checkbox"/>		
Receipt Description:			
Associated with e-Submission pkg 5214. Application for registration			
Form A: <input type="checkbox"/>	Signature Date:	Form B: <input type="checkbox"/>	Signature Date:

doc

D. O'Shaughnessy Consulting, Inc.

Product ingredient source information may be entitled to confidential treatment

Nov. 23, 2013

Dr. Tony Kish (PM 22)
US EPA, RD (7504P)
Rm. S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Dear Dr. Kish,

RE: Application to register "CY-MANCO 4-40 WDG FUNGICIDE" on behalf of Zenith Crop Sciences, SA, Liechtenstein (90332)

D. O'Shaughnessy Consulting, Inc. is listed by EPA as Agent for Zenith Crop Sciences and is authorized to make this application.

Enclosed is a DVD with an e-submission of an application to register the subject product. This product is a pre-mixture of co-fungicides (cymoxanil + mancozeb) already listed for use together as tank mixtures. The draft label has been worded to include only uses, rates and timing already allowed on cymoxanil (Curzate 352-592, Tanos 352-694) and mancozeb (Fortuna 75 WDG 89333-1, [REDACTED]). Accordingly, we believe that there remain no issues regarding food crop tolerances with the subject label.

Zenith Crop Sciences has provided the appropriate chemistry and acute toxicity data, and no end-use product specific data are cited from prior data submitters. The sources of both actives are to be purchased as registered sources, and so formulator's exemption will apply to generic data.

If you have any questions on this submission, please do not hesitate to contact me at the (Kentucky) co-ordinates on this letterhead.

Sincerely,



Don O'Shaughnessy, Ph.D., DABT

427 Hide Away Circle, Cub Run, KY 42729

207 Bank St., Ste 464, Ottawa, ON CANADA, K2P 2N2

Phone 270-524-5633 cell 270-537-5139

email: doctox@mac.com

www.regtoxinet

TRANSMITTAL DOCUMENT

1. Name and Address of Submitter

D. O'Shaughnessy Consulting, Inc., 427 Hide Away Circle, Cub Run, KY 42729
for
Zenith Crop Sciences, S.A.

2. Regulatory Action in Support of Which This Package is Submitted
Application to register CY-MANCO 4 - 40 WDG Fungicide

3. Transmittal Date
Oct. 14, 2013

4. List of Submitted Materials (e-submission on DVD)

Volume 1 of 10: Administrative materials (Cover letter, this Document, Application form, data matrix, Certification with respect to citation of data, Formulator's Exemption, CSF, draft labeling, PRIA fee check). **pre-assigned MRID 49214800**

Volume 2 of 10: Method of Formulation and Formation of Impurities **pre-assigned MRID 49214801**

Volume 3 of 10: Summary / Self Certification of Physical / Chemical Properties 1. **pre-assigned MRID 49214802**

Volume 4 of 10: Storage Stability and Enforcement Analytical Methods **pre-assigned MRID 4921403**

Volume 5 of 10: Acute oral toxicity **pre-assigned MRID 4921404**

Volume 6 of 10: Acute dermal toxicity **pre-assigned MRID 49214805**

Volume 7 of 10: Acute inhalation toxicity **pre-assigned MRID 49214806**

Volume 8 of 10: Primary dermal irritation **pre-assigned MRID 49214807**

Volume 9 of 10: Primary eye irritation **pre-assigned MRID 49214808**

Volume 10 of 10: Sensitization **pre-assigned MRID 49214809**

Transmitted by: Don O'Shaughnessy, Ph.D., DABT, DABFM



Contact Information: tel. 270.524.5633 cell 270.537.5139
email doctox@mac.com

PRIA 3 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

September 2012

21 Day Screen Start Date: 12/30/13

Experts In-Processing Signature: MP Date 1/3/14 Fee Paid: Yes

Division management contacted on issues No Yes Date

EPA Reg. Number: <u>90332-E</u>		EPA Receipt Date: <u>12/30/13</u>				
Items for Review				Yes	No	N/A*
1	Application Form (EPA Form 8570-1) signed & complete including package type			X		
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4)			X		
	a) All inerts, including fragrances, approved for the proposed uses (see Footnote A)	yes	no			
		X				
3	Certification with Respect to Citation of Data (EPA Form 8570-34) completed and signed (N/A if 100% repack)			X		
	Certificate and data matrix consistent			X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes	no			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	Formulator's Exemption Statement (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical)			X		
	Data Matrix (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack)			X		
5	a) Selective Method (Fee category experts use)	yes	no			
		X				
	b) Cite-All (Fee category experts use)					
	c) Applicant owns all data (Fee category experts use)					
6	5 Copies of Label (Electronic labels on CD are encouraged and guidance is available)			X		
7	Is the data package consistent with PR Notice 86-5			X		
8	Notice of Filing included with petitions					X

9	If applicable for conventional applications, <u>reduced risk rationale</u>			X
10	<u>Required Data</u> and/or data waivers. See Footnote C.			
	a) List study (or studies) not included with application			

Comments:

- * Inerts approved for food use under 40 CFR 180.920, pre harvest application to growing crops
- * submitted studies PASSED PRN 11-3 review
- * Jockey PASSED

lc

MRID: 492148

R 310

End Use (EP), or Manufacturing Use (MP) product or Technical Grade of the Active Ingredient (TGA):
Must submit Group A and B product chemistry data for each proposed product unless it's a 100% identical (repack): YES or NO (circle one)

Guideline No.	Group A: Product Chemistry Data Study Title	EP Data Submitted		MP Data Submitted		TGA	
		Yes	No	Yes	No	Yes	No
830.1550	Product Identity & Composition	X					
830.1600	Description of materials used to produce the product	X					
830.1650	Description of formulation process	X					
830.1670	Discussion on the formation of impurities	X					
830.1700	Preliminary analysis						
830.1750	Certified limits (158.345)	X					
830.1800	Enforcement analytical method	X					

Guideline No.	Group B: Product Chemistry Data Study Title	EP Data Submitted		MP Data Submitted		TGA	
		Yes	No	Yes	No	Yes	No
830.6302	Color	X					
830.6303	Physical State	X					
830.6304	Odor	X					
830.6313	Stability to normal and elevated temperatures metal and metal ions						
830.6314	Oxidation/Reduction (Chemical incompatibility)	X					
830.6315	Flammability	X					
830.6316	Explodability	X					
830.6317	Storage stability	X					
830.6319	Miscibility						
830.6320	Corrosion Characteristics	X					
830.6321	Dielectric Breakdown Voltage						
830.7000	pH	X					
830.7050	UV/ Visible Absorption						
830.7100	Viscosity						
830.7200	Melting Point						
830.7220	Boiling Point						
830.7300	Density	X					
830.7370	Dissociation Constant						
830.7550	Partition Coefficient						
830.7840	Water Solubility						
830.7950	Vapor Pressure						

Grayed out = data not required

R 310

New products must either: 1) supply the product specific acute toxicity 6 pack data (listed below), or 2) provide a bridging rationale document. The bridging document directs OPP to use a currently registered set of 6 acute toxicity data and label; instead of submitting product specific data.

Guideline No.	Acute toxicity (6 pack) Study Title	Data submitted		Cited	
		Yes	No	Yes	No
870.1100	Acute Oral (LD50)	X			
870.1200	Acute Dermal (LD50)	X			
870.1300	Acute Inhalation (LC50)	X			
870.2400	Acute Eye Irritation	X			
870.2500	Acute Dermal Irritation	X			
870.2600	Dermal Sensitization	X			

Efficacy - which guideline is used depends on the proposed label use

Guideline No.	Study Title	Data submitted		Cited		Comments
		Yes	No	Yes	No	
810.3100	Soil Treatments for Imported Fire Ants					N/A
810.3200	Livestock, Poultry, Fur and Wool-Bearing Animal Treatments					
810.3300	Treatments to Control Pests of Humans and Pets					
810.3400	Mosquito, Black Fly, and Biting Midge (Sand Fly) Treatments					
810.3500	Premises Treatments					
810.3600	Structural Treatments					
810.3800	Methods for Efficacy Testing of Termite Baits					



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

January 2, 2014

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OPP Decision Number: D-486410
EPA File Symbol or Registration Number: 90332-E
Product Name: cY MANCO 4-40 WDG FUNGICIDE
EPA Receipt Date: 30-Dec-2013
EPA Company Number: 90332
Company Name: ZENITH CROP SCIENCES, S.A.

DON O'SHAUGHNESSY, PH.D
D. O'SHAUGHNESSY CONSULTING, INC
ZENITH CROP SCIENCES, S.A.
427 HIDE AWAY CIRCLE
CUB RUN, KY 42729-

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R310

NEW END-USE OR MANUFACTURING USE PRODUCT WITH REGISTERED SOURCE(S) OF ACTIVE INGREDIENT(S);INCLUDES PRODUCTS CONTAINING TWO OR MORE REGISTERED ACTIVE INGREDIENTS PREVIOUSLY COMBINED IN OTHER REGISTERED PRODUCTS;REQUIRES REVIEW OF DATA PACKAGE WITHIN RD ONLY;INCLUDES DATA AND/OR WAIVERS OF DATA FOR ONLY;;PRODUCT CHEMISTRY;ACUTE TOXICITY;PUBLIC HEALTH PEST EFFICACY);CHILD RESISTANT PACKAGING;

No additional payment is due at this time. Unless it becomes necessary to revise the PRIA code assigned to this action, we will process a refund of your \$1,262 overpayment after processing has been completed.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-9362.

Sincerely,

A handwritten signature in cursive script, appearing to read "Teresa Downs", is written over the printed name.

Front End Processing Staff

Information Technology & Resources Management Division

Commercial/financial information may be entitled to confidential treatment

D. O'SHAUGHNESSY CONSULTING, INC. 427 HIDEAWAY CIRCLE CUB RUN, KY 42729-8692 (270) 524-5633		2444
DATE <u>12/23/13</u>		73-36-839
PAY TO THE ORDER OF <u>-US-EPA</u>	\$ <u>6310.00</u>	
<u>-SIX-THOUSAND-THREE-HUNDRED-TEN</u>		<u>63</u> DOLLARS
usbank. All of us serving you		
FOR <u>(CY-HAWK)</u> 90332-X R-314	NOT NEGOTIABLE	
⑈002444⑈		

Downs, Teresa

From: Don O'Shaughnessy [doctox@mac.com]
Sent: Tuesday, December 31, 2013 12:56 PM
To: Downs, Teresa
Subject: Re: application to register CY-MANCO 4-40 WDG FUNGICIDE (EPA file symbol 90332-E)
Attachments: cymancocheck.pdf; ATT00001.htm

The Cy-Manco was submitted in a separate envelope but on the same day (Dec. 23, second day air UPS) as Cy-Cop 90332-R. I had a call from Geri McCann saying the xml file did not open, so I sent a new DVD but not new check on Dec 27. The original check is likely clipped to 90332-R or something like that. Meanwhile here is a copy. If it does not get cashed in the next while, I will stop payment and send a new one.

Fee for Service

{945498a~

This package includes the following

☒ New Registration

☐ Amendment

☒ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: _____

for Division

☐ AD

☐ BPPD

☒ RD

Risk Mgr. 22

Réceipt No.

S-

945498

EPA File Symbol/Reg. No.

90332-E

Pin-Punch Date:

12/30/2013

☐ This item is NOT subject to FFS action.

Action Code:

Requested:

R310

Granted:

R310

Amount Due: \$ 5048.¹⁰

Parent/Child Decisions:

☒ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: 

Date: 12-31-13

Remarks:

- return for recoding this
the first time the SUBMISSION
have been formulated together

Receipt for Section 3

S: 945498

Milestone Email:

Regulatory Type: Product Registration - Section 3

Resubmission: ☐ Yes ☒ No

Application Type: New Registration

Fee For Service: ☒ Yes ☐ No

Billable: ☒ Yes ☐ No

Company: 90332 ZENITH CROP SCIENCES, S.A.



Print Letter

Enter More Information

Tracking

Risk Manager: Registration Division, Risk Management Team 22

Product #: 90332-E Product Name: CY MANCO 4-40 VDG FUNGICIDE

Override#:

Me Too

Section 3: Product Name:

Application Date: 27-Dec-2013

OPP Rec'd Date: 30-Dec-2013

Front End Date: 30-Dec-2013

Risk Manager Send Date:

FES Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track:

New Ingredient:

Receipt Description:

Associated with e-Submission pkg 5214. Application for registration

New Ingredient:

Request Date:

New Ingredient:

Received Date:

Form A:

Signature Date:

Form B:

Signature Date:

Receipt Content	
Study	
CSF	

View/Edit

E-SUBMISSION

doc

D. O'Shaughnessy Consulting, Inc.

Product ingredient source information may be entitled to confidential treatment

Nov. 23, 2013

Dr. Tony Kish (PM 22)
US EPA, RD (7504P)
Rm. S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

*Replacement DVD per
discussion Dec 27
2013
DD*

Dear Dr. Kish,

RE: Application to register "CY-MANCO 4-40 WDG FUNGICIDE" on behalf of Zenith Crop Sciences, SA, Liechtenstein (90332)

D. O'Shaughnessy Consulting, Inc. is listed by EPA as Agent for Zenith Crop Sciences and is authorized to make this application.

Enclosed is a DVD with an e-submission of an application to register the subject product. This product is a pre-mixture of co-fungicides (cymoxanil + mancozeb) already listed for use together as tank mixtures. The draft label has been worded to include only uses, rates and timing already allowed on cymoxanil (Curzate 352-592, Tanos 352-694) and mancozeb (Fortuna 75 WDG 89333-1, [REDACTED]). Accordingly, we believe that there remain no issues regarding food crop tolerances with the subject label.

Zenith Crop Sciences has provided the appropriate chemistry and acute toxicity data, and no end-use product specific data are cited from prior data submitters. The sources of both actives are to be purchased as registered sources, and so formulator's exemption will apply to generic data.

If you have any questions on this submission, please do not hesitate to contact me at the (Kentucky) co-ordinates on this letterhead.

Sincerely,



Don O'Shaughnessy, Ph.D., DABT

E-SUBMISSION

427 Hide Away Circle, Cub Run, KY 42729

207 Bank St., Ste. 464, Ottawa, ON CANADA K2P 2N2

Phone 270-524-5633

cell 270-537-5139

email docto@mac.com

www.regtox.net

TRANSMITTAL DOCUMENT

1. Name and Address of Submitter

D. O'Shaughnessy Consulting, Inc., 427 Hide Away Circle, Cub Run, KY 42729
for
Zenith Crop Sciences, S.A.

2. Regulatory Action in Support of Which This Package is Submitted
Application to register CY-MANCO 4 - 40 WDG Fungicide

3. Transmittal Date
Oct. 14, 2013

4. List of Submitted Materials (e-submission on DVD)

Volume 1 of 10: Administrative materials (Cover letter, this Document, Application form, data matrix, Certification with respect to citation of data, Formulator's Exemption, CSF, draft labeling, PRIA fee check). **pre-assigned MRID 49214800**

Volume 2 of 10: Method of Formulation and Formation of Impurities **pre-assigned MRID 49214801**

Volume 3 of 10: Summary / Self Certification of Physical / Chemical Properties 1 **pre-assigned MRID 49214802**

Volume 4 of 10: Storage Stability and Enforcement Analytical Methods **pre-assigned MRID 4921403**

Volume 5 of 10: Acute oral toxicity **pre-assigned MRID 4921404**

Volume 6 of 10: Acute dermal toxicity **pre-assigned MRID 49214805**

Volume 7 of 10: Acute inhalation toxicity **pre-assigned MRID 49214806**

Volume 8 of 10: Primary dermal irritation **pre-assigned MRID 49214807**

Volume 9 of 10: Primary eye irritation **pre-assigned MRID 49214808**

Volume 10 of 10: Sensitization **pre-assigned MRID 49214809**

Transmitted by: Don O'Shaughnessy, Ph.D., DABT, DABFM



Contact Information: tel. 270.524.5633 cell 270.537.5139
email doctox@mac.com

E-SUBMISSION



United States
Environmental Protection Agency
Washington, DC 20480

Registration
Amendment
Other

OPP Identifier Number

304921

Application for Pesticide - Section I

1. Company/Product Number 90332 - <u>E</u>	2. EPA Product Manager T. Kish	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Zenith Crop Sciences / CY-MANCO 4-40 WDG Fungicide	PM# 22	
5. Name and Address of Applicant (Include ZIP Code) Zenith Crop Sciences S.A., Aubünt 36, FL 9490 Vaduz, Liechtenstein <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Application to register a novel formulation of cymoxanil + mancozeb co-fungicides.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	
* Certification must be submitted				<input type="checkbox"/> Plastic	
If "Yes" Unit Packaging wgt. No. per container		If "Yes" Package wgt. No. per container		<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input checked="" type="checkbox"/> Other (Specify) foil lined paper bag	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 30 lb, 50 lb		5. Location of Label Directions <input type="checkbox"/> On Label <input checked="" type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph Paper glued Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Don O'Shaughnessy		Title Agent		Telephone No. (Include Area Code) 270-524-5633	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					8. Data Application Received (Stamped)
2. Signature 		3. Title Agent			
4. Typed Name Don O'Shaughnessy		5. Date 10-05-2013			



United States
Environmental Protection Agency
Washington, DC 20460

Formulator's Exemption Statement (40 CFR 152.85)

Applicant's Name and Address Zenith Crop Sciences, S.A. Aubündt 36, PO Box 880 FL 9490 Vaduz, Liechtenstein	EPA File Symbol/Registration Number 90332-x
	Product Name CY-MANCO 4 - 40 WDG Fungicide
	Date of Confidential Statement of Formula (EPA Form 8570-4) 09-30-2013

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s):

mancozeb cymoxanil, mancozeb

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another producer, and is labeled for at least each use for which my product is proposed to be labeled.

(3) Indicate by checking (A) or (B) below which paragraph applies:

- ☒ (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).
- OR**
- ☐ (B) The Confidential Statement of Formula (CSF) (EPA Form 8570-4) referenced above and on file with the EPA is complete, current, and accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

Source

Active Ingredient	Product Name	Registration Number
cymoxanil		
mancozeb		

Product ingredient source information may be entitled to confidential treatment

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Signature 	Name and Title Don O'Shaughnessy, Agent	Date 10-05-2013
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Zenith Crop Sciences, Abundt 36, FL-9490 Vaduz Liechtenstein, 011 41796863600	EPA Registration Number/File Symbol 90332- E
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Active Ingredient(s) and/or representative test compound(s) cymoxanil, copper hydroxide	Date 10/05/2013
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General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) outdoor food	Product Name CY-MAMNCO 4 -4 0 WDG Fungicide
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NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature

Date

10/05/2013

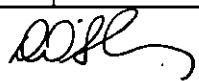
Typed or Printed Name and Title

Don O'Shaughnessy, Agent

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DATA MATRIX


Date 10-05-13			EPA Reg. No./File Symbol 90332-X		Page 1 of 2
Applicant's / Registrant's Name & Address Zenith Crop Sciences, S.A., Abündt 36, FL-9490 Vaduz, Liechtenstein			Product CY-MANCO 4 - 40 WDG Fungicide		
Ingredients cymoxanil, mancozeb					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.1550	Product Identity and Composition	(CSF) 49214800	Zenith Crop Sciences	OWN	
830.1600	Description of Materials Used to Produce the Product	49214801	Zenith Crop Sciences	OWN	
830.1620	Description of Manufacturing Process	49214801	Zenith Crop Sciences	OWN	
830.1670	Discussion of Formation of Impurities	49214801	Zenith Crop Sciences	OWN	
830.1750	Certified Limits	(CSF) 49214800	Zenith Crop Sciences	OWN	
830.1800	Enforcement analytical method	49214803	Zenith Crop Sciences	OWN	
830.6303	Physical State	49214802	Zenith Crop Sciences	OWN	
830.6304	Odor	49214802	Zenith Crop Sciences	OWN	
830.6320	Corrosion characteristics	49214802	Zenith Crop Sciences	OWN	
830.7300	Density	49214802	Zenith Crop Sciences	OWN	
830.6302	Color	49214802	Zenith Crop Sciences	OWN	
830.7000	pH	49214802	Zenith Crop Sciences	OWN	
830.6315	Flammability	49214802	Zenith Crop Sciences	OWN	
830.6316	Explosivity	49214802	Zenith Crop Sciences	OWN	
830.6317	Storage stability	49214803	Zenith Crop Sciences	OWN	
Signature 			Name and Title Don O'Shaughnessy, Agent		Date 10-05-13

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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6320	Corrosion characteristics	49214803	Zenith Crop Sciences	OWN	
830.6314	Oxidation / reduction potential	49214802	Zenith Crop Sciences	OWN	
870.1100	Acute oral toxicity	49214804	Zenith Crop Sciences	OWN	
870.1200	Acute dermal toxicity	49214805	Zenith Crop Sciences	OWN	
870.1300	Acute inhalation toxicity	49214806	Zenith Crop Sciences	OWN	
870.2500	Primary dermal irritation	49214807	Zenith Crop Sciences	OWN	
870.2400	Primary eye irritation	49214808	Zenith Crop Sciences	OWN	
870.2600	Sensitization	492148029	Zenith Crop Sciences	OWN	
Signature 			Name and Title Don O'Shaughnessy, Agent		Date 10-05-13

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			Zenith Crop Sciences	OWN	
			Zenith Crop Sciences	OWN	
			Signature 